Act explicitly indicates that the 2 to 3 year period for which categories of devices may be in effect applies from the first date on which payment was made under the OPPS for any device described by the category, which was August 2000.

Specific Category Applications

Comment: Several commenters commented on specific pass-through device category applications which we had open as of the time of the comment or applications which we had previously denied as eligible for pass-through payment.

Response: We evaluate all pass-through device category applications individually and respond to applicants directly.

D. Expiration of Transitional Pass-Through Payments in Calendar Year 2003 for Drugs and Biologicals (Including Radiopharmaceutical Agents, Blood, and Blood Products)

Under the OPPS, we currently pay for drugs and biologicals, including radiopharmaceutical agents, blood, and blood products, in one of three ways: packaged payment, separate APCs and transitional pass-through payment.

Drugs as Packaged Supplies

As we explained in the April 7, 2000 final rule, we generally package the cost of drugs and biologicals into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished (65 FR 18450). Hospitals do not receive separate payment from Medicare for packaged items and supplies, and hospitals may not bill beneficiaries separately for any such packaged items and supplies whose costs are recognized and paid for within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, a Program Memorandum issued to Intermediaries on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services.) Hospitals bill for costs directly related and integral to performing a procedure or furnishing a service using a revenue center or packaged HCPCS code (status indicator ''N''). As discussed earlier in section III.A.2 of the preamble, we list the packaged services, by revenue center, that we use to calculate per-service costs.

As specified in the regulations at § 419.2(b), costs directly related and integral to performing a procedure or furnishing a service on an outpatient basis are included in the determination of OPPS payment rates for the procedure or service. In the August 9, 2002 proposed rule, we provided some illustrations of situations in which drugs are considered to be supplies. For example, sedatives administered to patients while they are in the preoperative area being prepared for a procedure are supplies that are integral to being able to perform the procedure. Similarly, mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic ointments, and ocular hypotensives that are administered to the patient immediately before, during, or immediately following an ophthalmic procedure are considered an integral part of the procedure without which the procedure could not be performed. The costs of these items are packaged into and reflected within the OPPS payment rate for the procedure. Likewise, barium or low osmolar contrast media are supplies that are integral to a diagnostic imaging procedure as is the topical solution used with photodynamic therapy furnished at the hospital to treat non-hyperkeratotic actinic keratosis lesions of the face or scalp. Local anesthetics such as marcaine, lidocaine (with or without epinephrine) and antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure, are other examples we cited in the proposed rule. The hospital furnishes these items while the patient is in the hospital and registered as an outpatient for the purpose of receiving a therapy, treatment, procedure, or service. These and other such supplies may be furnished pre-operatively, while the patient is being prepared for a procedure; intra-operatively, while the procedure is being performed; or post-operatively, while the patient is in the recovery area prior to discharge. Or, these items may be part of an E/M service furnished during a clinic visit or in the emergency department. All of these supplies are directly related and integral to the performance of a separately payable therapy, treatment, procedure, or service with which they are furnished. Therefore, we do not generally recognize them as separately payable services. We package their cost into the cost of the primary procedure, and we pay for them as part of the APC payment.

We received several comments concerning the treatment of drugs as supplies, which are summarized below, along with our responses.

Comment: Several commenters asked for clarification of CMS's policy with respect to self-administered drugs, claiming the discussion in the preamble which lists examples of drugs, including self-administered drugs, that are packaged and paid as integral to an outpatient service conflicts with section 1861(s)(2) of the Act and CMS manuals which consider self-administered drugs to be non-covered.

Response: Our policy is based on the premise that certain drugs are so integral to a treatment or procedure that the treatment or procedure could not be performed without them. Because such drugs are so clearly a component part of the procedure or treatment, we believe that they are more appropriately considered as supplies and should be packaged as supplies into the APC payment for the procedure or treatment. Moreover, the payment for packaged supplies is included in the APC payment for the procedure or treatment, so beneficiaries should not be separately billed for them.

Comment: A commenter stated that virtually all drugs furnished in the outpatient setting are integral to an outpatient service and asked that CMS clarify those circumstances when usually self-administered drugs would not be considered integral to a service and therefore, non-covered.

Response: A drug would be treated as a packaged supply in cases where, although the drug is not separately payable, it is directly related and integral to a procedure or treatment and is required to be provided to a patient in order for a hospital to perform the procedure or treatment during a hospital outpatient encounter. A drug would not be treated as a packaged supply if it failed to meet these conditions. For example, we would not treat as packaged supplies any drugs that are given to a patient for their continued use at home after leaving the hospital. Another example would be a situation where a patient who is receiving an outpatient chemotherapy treatment develops a headache. Any medication given the patient for the headache would not meet the conditions necessary to be treated as a packaged supply. Similarly, if a patient who is undergoing surgery needs his or her daily insulin or hypertension medication, the medication would not be treated as a packaged supply.

Comment: A commenter from a teaching hospital indicated that revenue code 819, which is required for the acquisition of bone marrow or blood-derived peripheral stem cells, is bundled into the charge for the transplantation procedure, CPT 38240. The commenter noted that the transplant CPT code pays approximately $350–$400; however, charges for acquiring stem cells are generally $25,000–$35,000 each. Therefore, the commenter recommended that we create

a new biological pass-through code for the stem cells until we can build the cost of the acquisition into the procedure, and the code should be retroactive to January 1, 2002.

Comment: A commenter from a teaching hospital indicated that revenue code 819, which is required for the acquisition of bone marrow or blood-derived peripheral stem cells, is bundled into the charge for the transplantation procedure, CPT 38240. The commenter noted that the transplant CPT code pays approximately $350–$400; however, charges for acquiring stem cells are generally $25,000–$35,000 each. Therefore, the commenter recommended that we create a new biological pass-through code for the stem cells until we can build the cost of the acquisition into the procedure, and the code should be retroactive to January 1, 2002.

Response: We understand the commenter's concern. Pass-through payments, after December 31, 2002, will only be made for medical devices, drugs, or biologicals in accordance with section 1833(t)(6)(A)(iv) of the Act. Stems cells are not medical devices nor do they meet the statutory prerequisite for calling these items ''drugs and biologicals,'' as stated in sections 1861(t)(A) and (B) of the Act. For example, stems cells do not receive FDA approval and are not listed in the United States Pharmacopoeia.

The commenter indicates that the hospital is not being paid adequately for stem cell acquisition costs. However, the commenter should note that hospitals should be reporting all charges associated with the purchase of stem cells under Revenue Code 819. Therefore, to the extent that hospitals are billing a charge for the cost of acquiring stem cells under Revenue Code 819, those costs would be packaged into the median cost of CPT 38240 and be reflected in the APC payment rate. These services may also qualify for outlier payments.

Separate APCs for Drugs Not Eligible for Transitional Pass-Through Payment

There are certain new technology drugs and biologicals that are not eligible for transitional pass-through payments but for which we have made separate payment. Beginning with the April 7, 2000 rule (65 FR 18476), we created separate APCs for these drugs and biologicals as well as devices. We proposed to create temporary individual APC groups for the various drugs classified as tissue plasminogen activators and other thromobolytic agents that are used to treat patients with myocardial infarctions as well as certain vaccines to allow separate payment so as not to discourage their use where appropriate. In the case of blood and blood products, wide variations in patient requirements convinced us that we should pay for these items separately rather than packaging their costs into the procedural APCs. Moreover, the Secretary's Advisory Council on Blood Safety and Access recommended that blood and blood products be paid separately to ensure that to minimize incentives that would be inconsistent with the promotion of blood safety and access.

In the case of the other drugs and vaccines that we proposed not package into payment for visits or procedures, we paid separately for them because we wanted to avoid creating an incentive to cease providing these drugs when they were medically indicated.

We based the payment rate for the APCs for these drugs and biologicals on median hospital acquisition costs using 2001 claims data. We set beneficiary copayment amounts for these drug and biological APCs at 20 percent of the payment amount. In 2003 we will use status indicator ''K'' to denote the APCs for drugs and biologicals (including blood and blood products) and certain brachytherapy seeds that are paid separately from and in addition to the procedure or treatment with which they are associated but that are not eligible for transitional pass-through payment.

General

BBRA provided for special transitional pass-through payments for a period of 2 to 3 years for the following drugs and biologicals (pass-through payments for devices are addressed in section IV.C. of the preamble):

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.
- Current drugs and biologic agents used for treatment of cancer.
- Current radiopharmaceutical drugs and biological products.
- New drugs and biological agents.

In this context, ''current'' refers to those items for which hospital outpatient payment was being made on August 1, 2000, the date on which the OPPS was implemented. A ''new'' drug or biological is a product that is not paid under the OPPS as a ''current'' drug or biological, was not paid as a hospital outpatient service before January 1, 1997, and for which the cost is not insignificant in relation to the payment for the APC with which it is associated.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs as the amount by which the amount determined under section 1842(o) of the Act, that is, 95 percent of the applicable average wholesale price (AWP), exceeds the difference between 95 percent of the applicable AWP and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Therefore, in order to determine the pass-through payment amount, we first had to determine the cost that was packaged for the drug or biological within its related APC. In order to determine this amount, we used data on hospital acquisition costs for drugs from a survey that is described more fully in the April 7, 2000 and the November 30, 2001 final rules. The ratio of hospital acquisition cost, on average, to AWP that we used is as follows:

- For sole-source drugs, the ratio of acquisition cost to AWP equals 0.68.
- For multisource drugs, the ratio of acquisition cost to AWP equals 0.61.
- For multisource drugs with generic competitors, the ratio of acquisition cost to AWP equals 0.43.

Section 1833(t)(6)(C)(i) of the Act specifies that the duration of transitional pass-through payments for current drugs and biologicals must be no less than 2 years nor any longer than 3 years beginning on the date that the OPPS is implemented. Therefore, the latest date for which current drugs that have been in transitional pass-through status since August 1, 2000 will be eligible for transitional pass-through payments is July 31, 2003. We proposed to remove these drugs from transitional pass-through status effective January 1, 2003 because the statute gives us the discretion to do so and because we generally implement annual OPPS updates on January 1 of each year. We would be in violation of the law if we were to not remove these drugs and biologicals from transitional pass-through status by August 1, 2003. The next update of the OPPS that will go into place will not be effective until January 1, 2004, at which time the statute's 3-year limit on pass-through payments for these drugs would have been exceeded. We further proposed to remove from transitional pass-through status, beginning January 1, 2003, those drugs for which transitional pass-through payments were made effective on or prior to January 1, 2001 because the law gives us the discretion to do so and we believe that, to the extent possible, payments should be made under the OPPS, without pass-through payment, when the law permits, as it does in this case.

As explained above, our policy has been to package payment for drugs and

biologicals into the payment for the procedure or service to which the drug is integral and directly related. In general, packaging the costs of items and services into the payment for the primary procedure or service with which it is associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Packaging costs into a single aggregate payment for a service procedure or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Our proposal to package the costs of devices that we discuss in section IV.C of this preamble is based on this principle. As we refine the OPPS in the future, we intend to continue to package, to the maximum possible extent, the costs of any items and services that are furnished with an outpatient procedure or service into the APC payment for services with which it is billed.

In spite of our commitment to package as many costs as possible, we are aware of concerns that were presented at the April 5, 2002 Town Hall meeting and that have been brought to our attention by various interested parties, that packaging payments for certain drugs, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.

The options that we considered included packaging the costs of all drugs and biologicals, both those with status indicator ''K'' in 2002 and those that would no longer receive pass-through payments in 2003, or continuing to make separate payment for both categories of drugs and biologicals through separate APCs. After careful consideration of the various options for 2003, we proposed to package the cost of many drugs for which separate payment is made currently. But we also proposed to continue making separate payment for certain orphan drugs (as discussed below), blood and blood products, vaccines that are paid under a benefit separate from the outpatient hospital benefit (that is, influenza, pneumococcal pneumonia, and hepatitis B), and certain higher cost drugs as explained below. The payment rates for those drugs for which we would make separate payment in 2003 would be an APC payment rate based on a relative weight calculated in the same way that relative weights for procedural APCs are calculated.

Comments on this proposal and our responses are summarized below:

Comment: We received many comments regarding the significant reduction in the payment rates for numerous drugs and biologicals that are sunsetting from their transitional pass-through status. The commenters asserted that proposed payment rates are significantly lower than the costs hospitals incur in acquiring and dispensing these products. As a result, inadequate payment may drive hospitals to discontinue stocking these products, and thus threaten beneficiary access to important drugs and biologicals. The commenters attributed the dramatic reduction in payment rates on the flaws in the 2001 claims data and deficiencies in the methodology that was used to derive the APC median costs. Commenters suggested numerous ways to correct the payment rates until reliable and sufficient claims data became available. Commenters proposed the following suggestions: maintain separate pass-through payments for APCs whose proposed payment rates decreased; pay a flat amount per item on a per patient basis; develop a rate setting methodology that does not depend upon the hospital's ability to record the proper number of units of a drug utilized; use information provided by commenters to set the 2003 payment rates; revise payment rates to include payment for the drug and related pharmacy overhead costs; pay 90 to 100 percent of AWP for non-pass-through drugs; use an appropriate ratio of acquisition cost to AWP as estimated in the proposed rule; conduct a new external survey of hospitals' drug acquisition costs to obtain more current data; or pay according to the median hospital cost for the item.

Response: As discussed elsewhere in this rule, in order to lessen the impact of the dramatic reduction in the proposed payment rates for many of the drugs and biologicals from 2002 to 2003, we decided that the most appropriate mechanism is to apply a dampening option to all of the APCs that decreased in median costs by more than 15 percent. For these APCs, we limited the reduction in median costs from 2002 median costs to half of the difference between the total proposed reduction and 15 percent. However, budget neutrality adjustments needed to compensate for the effects of this dampening subsequently reduced payment rates of all APCs by an additional percentage. Also, we applied a special dampening option to all blood and blood products and hemophilia clotting factors that limited the decrease in their payment rates to about 15 percent. These adjustments yielded significant moderation in the reduction of the final 2003 payment rates. These adjustments are described in detail in section III.B of the preamble.

After carefully reviewing all of the comments, a dampening option seemed most plausible and practical for us to undertake. Most of the recommendations proposed by the commenters were not feasible or not suitable for the purposes of OPPS.

Comment: Many commenters indicated that the median costs derived from the claims data was not reflective of the hospitals' true costs for acquiring and dispensing these drugs and biologicals.

Response: We agree with this point; however, the commenters should note that we intend to pay only for the cost of acquiring the drug under a drug APC and not for costs associated with the administration of the drug. Costs associated with administering the drug and with other pharmacy overhead are captured in pharmacy revenue cost centers and reflected in the median cost of APCs involving drug administration. Therefore, we believe that it is not appropriate for us to duplicate these costs in both the administration and drug APCs.

Comment: Several commenters noted that many drugs and biologicals were packaged into administration APCs; however, they were surprised to see decreases in the proposed payment rates for several of the administration APCs. The commenters stated that the addition of the costs of the packaged products should have caused the APC median cost levels to increase, thus their payment rates should have also increased compared to 2002. However, the commenters assert that the proposed payment rates for several administration APCs in which the drugs were packaged does not adequately cover the acquisition cost of the drugs themselves. Thus, they recommended that we reevaluate our data to ensure that costs of the packaged drug were included with the data for the applicable administration APCs, or otherwise explain how we plan to reimburse hospitals for the costs of the packaged drugs; retain the 2002 payment rates for administration services and pay for the drugs separately; or use our authority to limit any payment reductions for certain services. One commenter suggested that we conduct a survey of cancer centers to determine the true cost of infusion procedures and make an adjustment to the APC rates based on our finding.

Response: After reanalyzing our data, we were able to verify that the median costs of the drugs were indeed packaged into the median costs of the

administration APCs. We acknowledge that the median costs of several administration APCs before we packaged drug costs declined between those median costs used to set the 2002 rates and those median costs developed from the 2001 claims for the 2003 rates. This decline occurred because, in setting the 2002 rates, we packaged in 75 percent of the cost of pass through devices we projected would be billed with the administration codes, based on manufacturer prices. The 2001 claims data, however, did not reflect the charges that we predicted would be billed for such devices. An increase in the median cost of a service does not guarantee that the payment rate for the service will increase because payment rates under the OPPS are based on relative costs and the budget neutrality adjustment. If the relative cost of a service increases at a lower rate than other services, the payment rate may actually decline. In addition, all rates are affected by the budget neutrality adjustment that has lowered rates over the past several years. (We note that it is possible for the budget neutrality adjustment to increase rates as occurred in the proposed rates.) As noted elsewhere, for APCs whose median costs decreased by more than 15 percent from 2002 to 2003, the dampening option described elsewhere in this rule limits the decreases in their payment rates.

Comment: A commenter requested that we describe the methodology used to calculate the payment rates for sunsetting pass-through drugs that are being assigned to separate APCs.

Response: We have provided a detailed description of the methodology we used in the calculation of the APC payment rates for sunsetting drugs and biologicals in section III.B of the preamble.

Comment: A major hospital association supported our proposal to incorporate pass-through drugs into APC rates. However, the commenter was concerned that many of these same drugs would continue to receive 95 percent of AWP in other settings, and differential payments may result in patient care being directed out of the hospital outpatient setting and into physician offices for non-clinical reasons.

Response: We believe that the payment rates for sunsetting pass-through drugs and biologicals reflect hospital acquisition cost to a sufficient extent so that hospitals will not, in general, stop furnishing these products to beneficiaries. While Medicare payment in other settings will be higher, the extent of response that may be expected to these payment differentials is unclear. We note that the same differentials prevailed for years prior to the introduction of the outpatient prospective payment system. We believe that the appropriate policy response is to address the use of AWP as a basis for payment in non-hospital sites.

Comment: A state hospital association indicated that confusion exists among hospitals over which drugs can be self-administered and that instructions from fiscal intermediaries are inconsistent and/or confusing. The commenter requested that we publish a definitive list of drugs that are to be considered to be self-administrable, and thus is not part of covered services. Another commenter from a hospital urged us to clarify whether self-administrable drugs (both those that are integral and non-integral to the patient's procedure) in outpatient and observation settings are the patient's responsibility or should be packaged under procedure APCs. Another commenter from a hospital organization suggested that we exempt hospitals from determining which drugs should be classified as self-administered or allow hospitals to classify drugs based on the dosing form and pursue payment from the beneficiary.

Response: On May 15, 2002, we issued Transmittal AB–02–072 entitled ''Medicare Payment for Drugs and Biologicals Furnished Incident to a Physician's Service.'' The program memorandum gives instructions to the fiscal intermediaries for applying the exclusion to drugs that are usually self-administered by the patient. Each fiscal intermediary makes its determination on each drug based on whether the drug meets all of the program requirements for coverage. The payment rates that we are finalizing in this rule only indicate the Medicare payment amounts under OPPS when a drug is covered by Medicare; therefore, determination of a payment amount does not represent a determination that the Medicare program covers the drug. We discuss elsewhere in this preamble how Medicare makes payments for drugs that are considered to be supplies.

Comment: Several commenters suggested that we publish various sorts of additional information about the methodology we used to calculate the payment rates, including technical details of the methodology used in analysis of the 2001 claims.

Response: We do not believe the final rule is the appropriate vehicle for conveying the extensive background technical detail that may be of interest to the analytical community. However, we plan to hold a meeting in December 2002 or January 2003 to address the questions these commenters or other interested parties may have about our methodology.

Comment: Several commenters were concerned that fiscal intermediaries have addressed the issue of drug units of service with respect to billing and waste differently, and requested that we provide clear and consistent guidance to the fiscal intermediaries as well to providers on how to define ''waste.''

Response: In the fall of 1996, we issued a memorandum to our regional offices with guidance regarding our current policy on drug and biological product wastage. Although this memorandum focused on guidance for carriers, it overall reflects our current policy for drug and biological product wastage.

We recognize that some drugs may be available only in packaged amounts that exceed the needs of an individual patient. Once the drug is reconstituted in the hospital's pharmacy, it may have a limited shelf life. Since an individual patient may receive less than the fully reconstituted amount, we encourage hospitals to schedule patients in such a way that the hospital can use the drug most efficiently. However, if the hospital must discard the remainder of a vial after administering part of it to a Medicare patient, the provider may bill for the amount of drug discarded along with the amount administered.

Example 1: Drug X is available only in a 100-unit size. A hospital schedules three Medicare patients to receive drug X on the same day within the designated shelf life of the product. An appropriate hospital staff member administers 30 units to each patient. The remaining 10 units are billed to Medicare on the account of the last patient. Therefore, 30 units are billed on behalf of the first patient seen and 30 units are billed on behalf of the second patient seen. Forty units are billed on behalf of the last patient seen because the hospital had to discard 10 units at that point.

Example 2: An appropriate hospital staff must administer 30 units of drug X to a Medicare patient, and it is not practical to schedule another patient who requires the same drug. For example, the hospital has only one patient who requires drug X, or the hospital sees the patient for the first time and did not know the patient's condition. The hospital bills for 100 units on behalf of the patient, and Medicare pays for 100 units.

Comment: A few commenters urged us to provide a crosswalk identifying which drugs are being associated with which APCs and in what amounts, to help ensure that costs are being appropriately transferred to and allocated among APCs.

Response: Our methodology did not rely on a crosswalk, and we do not have one available. In our methodology, we

packaged drugs and biologicals that fell below the $150 median cost per line threshold into the procedure APCs they were billed from April 1, 2001 to March 31, 2002. Interested parties may analyze the claims data that is available to the public to determine the extent to which the costs of specific drugs and biologicals were included in payment rates of the procedure APCs.

Comment: A commenter expressed concern related to the adenosine products J0150 and J0151. The commenter stated that although these two codes reflect different uses and doses of the adenosine products, OPPS only recognizes billing only under the lowest dose of J0150 and J0151 is assigned a status indicator of E. Consequently, the hospitals have been billing for both products under code J0150. The commenter requested that we clear the confusion that exists among hospitals when billing for these products by reinstating J0151 under a separately paid APC with an adequate payment rate and revising J0150 so that the code is specific to its actual use.

Response: After reviewing the comment, we assigned a status indicator of N to J0150 to indicate that J0150 will be packaged in 2003; and changed the status indicator for J0151 from E to K and assigned it to APC 0917.

Comment: One commenter requested that we update the HCPCS description for all drugs to accurately report all medications in the way manufacturers currently package them. The commenter claimed that our current use of codes causes confusion and has the potential to create reimbursement problems for providers and the Medicare program.

Response: To the extent possible, when creating the ''C'' codes used to report drugs and biologicals eligible for transitional pass-through payment under OPPS, we employ the lowest common measurement of dosage for each drug so that hospitals can bill the number of units that are required to treat the patient by using multiple units of a single code. As drugs and biologicals retire from pass-through status, we expect to retire the ''C'' codes for these items. We expect these items will receive appropriate ''non-C'' HCPCS codes.

Comment: Several commenters claimed that our proposal to package many of the non-pass-through, lower cost drugs and biologicals with HCPCS codes for therapeutic administration is a violation of the ''two-times'' rule. Therefore, they recommended that we continue to pay for all drugs and biologicals separately or by revising the APCs in which the drugs are packaged.

Response: We do not agree with the commenters' assertion that packaging of drugs and biologicals results in violations of the two-times rule, stated in section 1833(t)(2) of the Act. We understand the commenters' confusion and attempt to provide a clarification on how we apply the ''two-times'' rule to determine APC structures. Most APC's consist of one or more services, which reported with CPT or HCPCS G codes, that are similar clinically and in terms of resource use. Many individual items (for example, sterile supplies or pharmaceuticals such as anesthetic agents) are integral to the procedure, and thus we have packaged them with the procedure. In some instances, such as APCs for transitional pass-through drugs and devices, the APC includes no procedure, and the APC is used only to pay for a specific item.

The ''two times'' rule requires that the highest median cost of a service or item within an APC cannot be more than two times greater than the lowest median cost of a service or item within that APC. We apply the ''two-times'' rule to the total cost of each procedure (which includes items that are packaged within that procedure). In the case of APCs containing only items, we apply the rule to the cost of each item that is grouped in the APC. We do not apply the two times rule to the variation in cost of individual items or ancillary services we attribute to a single HCPCS code.

If we were to attempt to apply the rule to all items within the various procedures, accounting for the variation in cost of supplies such as bandages, reusable instruments, and other medical supplies would be a practical impossibility. It would lead to a highly fragmented set of payment cells and a greatly more complex payment system that would reduce the incentives for effective management by hospitals. We do not believe the Congress would have intended such a result.

Consistent with the principles of prospective payment, we package the cost of as many items as possible into the median cost of a procedure. Therefore, our payment methodology for 2003 includes packaging the costs of drugs and biologicals with median costs below $150 per line into the costs of the procedures with which they were billed. We reviewed the median cost of the procedures used for administration of drugs and biologicals, before and after we packaged the costs of drugs and biologicals. Our review indicates that the final median cost appropriately accounts for the administration procedure and the cost of the administered drug and/or biologic.

Comment: Numerous commenters were concerned about the proposed reduction in payment rates for several radiopharmaceutical products. They asserted that hospitals would not be reimbursed adequately for these products, and thus, beneficiary access could be negatively impacted. They recommended that we should not base payments on the 2001 claims data and use a different methodology instead. They suggested that we estimate acquisitions costs using the proposed ratios for acquisition cost to AWP based on analysis conducted by the agency; maintain the 2002 payment levels; or create new APCs using cost ranges and assign radiopharmaceuticals to APCs based on their costs, as determined by AWP plus overhead fees, or another proxy for actual hospital costs.

Response: We are concerned about the possible effects of payment reductions on beneficiary access, and accordingly, we have included radiopharmaceuticals in the dampening policy described section III.B. of the Preamble.

Comment: Several commenters were concerned with our proposal to package numerous radiopharmaceutical products. They claimed that given the problems with the claims data and the great variation in the cost and use of radiopharmaceuticals for the same procedure, all radiopharmaceuticals should be paid under their own APCs, in addition to their associated nuclear medicine procedures. This would assure appropriate reimbursement for both the product and procedure, and would be the best way to capture hospital costs for radiopharmaceuticals in future claims data.

Response: While we acknowledge the commenters' concerns, we believe that the most appropriate payment structure is one that packages services together to the extent it is reasonable to do so, and thus presents hospitals with bundled payments that permit them to effectively manage resource allocation in the treatment of particular patients. Accordingly, we have not adopted this suggestion.

Comment: A manufacturer and a trade association suggested that we could improve the accuracy of the APC payment rates by establishing new revenue codes to accurately capture data and calculate costs for radiophamaceuticals in future years.

Response: While we do want to improve the accuracy of APC payment rates, we are reluctant to impose new requirements on hospital cost reports. In addition, the creation of new revenue centers must be made through a process that includes other payers as well as representatives of various providers.

Therefore, we will not adopt this suggestion for 2003. As discussed in section III. B of this final rule, we expect to address the issue of improving the accuracy of our data further in the future.

Comment: A hospital organization indicated that there is a competitive disadvantage between different types of providers (clinic, Independent Diagnostic Testing Facilities (IDTF), and outpatient hospital) and their payment policies for Low Osmolar Contrast Media (LOCM). The commenter stated that in a clinic or IDTF, LOMC receives separate payment when clinical conditions are met. However, when LOCM is administered in an outpatient hospital without an intrathecal procedure or if one of the Medicare coverage conditions is non-covered, hospitals are expected to issue an ABN to the patient. The commenter recommended that we allow hospitals to bill for LOCM even when the patient does not meet conditions, or instruct the clinics and IDTFs to seek ABNs for LOCM in non-covered circumstances. A state hospital association suggested that we eliminate the medical necessity requirement for LOCM since it is not applicable to hospital outpatient services.

Response: These suggestions involve several different Medicare payment systems, and appropriate resolution of this concern will require further analysis. We will consider this issue further in the future.

Comment: One commenter requested clarification on whether there will be any more changes to the payment calculation for HCPCS C1775 (FDG, per dose) other than what is proposed in Table X of the proposed rule.

Response: According to our new policy for radiopharmaceuticals, as described elsewhere in this final rule, FDG will no longer be granted pass-through status in 2003. It will instead be paid separately under its own APC and be assigned to a status indicator of K.

Comment: Another commenter requested that we describe our waste policy on whether a hospital may bill for a medication that is ordered and mixed, but not administered to the patient due to a change in patient status or a no-show by the patient for that day's visit. If the drug cannot be used later or on another patient, the hospital would still incur the costs.

Response: If the drug is not administered to a Medicare beneficiary, then payment may not be made by the Medicare Program.

Packaging Issue

Comment: Several commenters indicated that our methodology of analyzing single line-items on drug claims is not consistent with how hospitals bill for certain particular drugs and biologicals. This inconsistency particularly affects whether a drug or biological falls below the $150 median cost per line threshold or not. They claimed that we incorrectly assumed ''that a single administration of a drug was billed as a single line item on a claim and that the correct number of units was placed in the 'units' field of the claim form.'' Commenters noted that this was not always true because hospitals often bill for certain drugs using multiple lines in a claim that represents one patient encounter. They indicated that in our calculation of the median cost per line for a drug, we multiplied the median cost per unit of the drug by the average number of units billed per line. Thus, our methodology does not take into account all of the units of a drug administered during one encounter if the units were billed in multiple lines on the claim, and consequently, may not reflect the full cost of delivering the drug.

Response: For 2003, we chose to use the $150 median cost per line threshold level to determine whether to package a drug, as opposed to another packaging criterion, for the reasons of administrative simplicity, administrability, and responsiveness. However, in our analysis of the data, we observed that instances where a drug was billed on multiple lines in a claim were rare (less than 1 percent of total billings for drugs). We reiterate that our intent is to review and refine the packaging methodology in the future and will take the commenters' concern into account.

Orphan Drugs

We recognize that orphan drugs that are used solely for an orphan condition or conditions are generally expensive and, by definition, are rarely used. We believe that if the cost of these drugs were packaged into the payment for an associated procedure or visit, the payment for the procedure might be insufficient to compensate a hospital for the typically high cost of this special type of drug. Therefore, we proposed to establish separate APCs to pay for those orphan drugs that are used solely for orphan conditions.

To identify the orphan drugs for which we would continue to make separate payment, we applied the following criteria:

- The drug must be designated as an orphan drug by FDA and approved by FDA for the orphan condition.
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug had neither an approved use for other than an orphan condition nor an off label use for conditions other than the orphan condition. There are three orphan drugs that are used solely for orphan conditions for which we proposed to make separate payment: J0205 Alglucerase injection; J0256 Alpha 1 proteinase inhibitor; and J09300 Gemtuzumab ozogamicin.

Comment: Several commenters stated that the proposed payment rates for the orphan drugs would grossly underpay hospitals for providing these drugs to patients. They recommended that we pay for orphan drugs according to current year acquisition and actual total costs of providing the products; maintain the 2002 payment levels; or remove from them from the OPPS system and set payment according to the methodology used in the physician office and other non-inpatient settings.

Response: After reviewing the comments, we have decided to remove the three orphan drugs that do not have any other non-orphan indications from the OPPS system and will pay for them on a reasonable cost basis. Other drugs that have orphan status according to the FDA will be partly protected by the dampening options described in section III.B of this final rule.

Comment: Several commenters objected to what they characterized as our definition of ''orphan drug.'' These commenters believe we should treat comparably all drugs and biologicals that have been designated as under section 526 of the Federal Food, Drug, and Cosmetic Act.

Response: We emphasize that we are not creating a new definition of orphan drugs; instead, we continued to rely on the definition stated in the Federal Food, Drug, and Cosmetic Act. However, within the set of drugs that the FDA has identified as orphan drugs, we have identified a subset of three drugs that have only orphan indications and decided to remove them from the outpatient prospective payment system. We have distinguished these drugs from other orphan drugs because of their low volume of patient use and their lack of other indications, which means they can rely on no other source of payment. Many orphan drugs are approved for multiple indications, including non-orphan indications that have significant patient use that provide the drugs with financial support. For example, epoetin alfa was originally identified as an

orphan drug for use in ESRD patients; however, currently it is being used extensively in patients with chemotherapy-induced anemia. Once a drug is granted orphan status, no further effort is made to update this status, even though indications for use may change substantially with experience. After consulting with our clinical advisors, we have decided to remove from OPPS the three orphan drugs that have no other non-orphan indications. We recognize the importance of all orphan drugs, however, and accordingly we have applied the dampening policies described in section III.B of the preamble to the other orphan drugs.

Blood and Blood Products

From the onset of the OPPS, we have made separate payment for blood and blood products either in APCs with status indicator ''K'' or as pass-through drugs and biologicals with status indicator ''G'' rather than packaging them into payment for the procedures with which they were administered. As we explained in the April 7, 2000 final rule (65 FR 18449), the high degree of variability in blood use among patients could result in payment inequities if the costs of blood and blood products were packaged with their administration. We also want to ensure that costs associated with blood safety testing are fully recognized. The safety of the nation's blood supply continues to be among the highest priorities of the Secretary's council on Blood Safety and Access. Therefore, we proposed to continue to pay separately for blood and blood products.

Comment: Several major blood collection organizations, specialty physician groups, a large trade association, hospital associations, and individual hospitals supported our decision to maintain separate APCs for blood and blood products; however, the commenters were concerned with the reduction in payment rates for these products in the proposed rule.

The commenters provided several suggestions. They recommended that we base the payment rates for blood products on current year acquisition costs and actual total costs rather than on hospital claims from previous years, and use industry data on the current hospital costs of blood and blood products that have been submitted to us; consider costs related to additional costs that hospitals incur in storing and preparing units for transfusion when assigning APC relative weights to blood and blood products; continue the 2002 payment rates until more accurate information on the actual costs of blood and blood products are gathered; or reimburse hospitals on a reasonable cost basis for blood and blood products.

Response: After carefully reviewing the comments and comparing the industry data against our data, we were convinced that the proposed reduction in payment rates for many of the blood and blood products would result in payment that is significantly lower than hospital acquisition costs. Thus, inadequate reimbursement may compromise access to beneficiaries and the safety of these products. We continue to be aware of the variability in the use of blood and blood products in various procedures, and by our desire to recognize costs of new tests being performed on blood, we have decided to apply a special dampening option to blood and blood products that had significant reductions in payment rates from 2002 to 2003. For these products, as described in section III.B of the preamble, we limited the decrease in their median costs by 11 percent, which limited the decrease in payment rates to approximately 15 percent. We note that the APCs for these products are intended to cover product costs; costs for storage, etc., are packaged into the APCs for the procedures with which the products are used.

Comment: A commenter from an individual hospital disagreed with our proposal to not change the current OPPS payment policy for transfusions. The commenter stated that their hospital has more than the average number of cases that require more than one unit of blood, and thus, averaging the payment would adversely affect specialty hospitals.

Response: For transfusion services that are paid under OPPS, hospitals can bill for the administration of the transfusion and the number of units of blood transfused. With the payment rates for transfusion and blood and blood products that are in the final rule, we believe that hospitals, including those that specialize in the transfusion of multiple units of blood, will receive adequate payment for transfusion services. The hospitals will receive separate payment for the blood in addition to the APC payment for the transfusion service. Even though we will not change our payment policy for transfusions for 2003, this is an issue that we will continue to monitor in the future.

Comment: Two commenters requested that we provide special comprehensive billing and coding guidelines in the area of blood, blood processing, and transfusion medicine, and the proper use or non-use of the transfusion medicine codes. They stated that Transmittal A–01–50 does not clarify all of the confusing issues that hospitals currently experience in billing and coding for blood-related services.

Response: We acknowledge that need for comprehensive billing and coding guidelines in the areas mentioned by the commenters and agree that the program memorandum that was issued previously may require further clarification. Therefore, this is an area that we expect to focus on during the upcoming year.

Comment: Several hospitals, advocacy organizations, manufacturers, and beneficiaries were concerned that the proposed decrease in reimbursement for certain clotting factors would not enable hospitals to recover the acquisition costs of the products. They indicated that inadequate reimbursement would create incentives for hospitals to not provide these products at all or to provide only those clotting factors that limit financial loss. Commenters also indicated that given the high cost of the clotting factors, the average cost to charge ratio methodology that might apply to other drugs does not apply to clotting factors, and the proposal would shift patients to the inpatient setting where costs of care are higher. Their recommendations were that we adjust the proposed payment with a rate consistent with the average acquisition cost of the drugs; maintain the 2002 payment rates; use current hospital inpatient payment rates in place of the proposed rates; or remove from the OPPS system and set payment according to the methodology used in the physician office and other non-inpatient settings.

Response: We recognize the importance of insuring adequate reimbursement and access to hemophilia clotting factors for our beneficiaries, as did the Congress when it created a separate benefit category for clotting factors in section 1861(s)(2)(I) of the Act. Accordingly, we have adopted a provision to insure that the payment rates for these products does not decrease by more than approximately 15 percent from 2002 to 2003.

Comment: Several commenters were very concerned with the proposed payment rates for plasma products and their recombinant analogs therapies. They argued that reduction in payments would create significant patient access problems since the hospitals will be unable to recoup costs incurred in acquiring and dispensing such therapies. They recommended that we pay for these products on a reasonable cost basis; revise the payment rates significantly to allow hospitals to recover their acquisition and dispensing costs; base payment on current acquisition costs and actual total costs

of the products in outpatient settings; maintain payment at the 2002 level; or establish an add-on payment to be based on a national formula derived outside of OPPS.

Response: We recognize the importance of these drugs, and consequently included them in the dampening procedure described section III.B of the preamble.

Comment: Several commenters urged us to clarify the category of ''blood and blood products'' to include drugs and biologicals that are derived from plasma fractionation and their biotechnology analogs. They stated that the rationale for creating separate APCs for blood and blood products also equally apply to plasma-based products and their recombinant therapies. These commenters recommended that we continue to pay for all plasma-derived and recombinant analog therapies in separate APCs and include them in the category of ''blood and blood products'' as it is done under the FDA's definition of ''blood and blood products.''

Response: We acknowledge that plasma-based products and their recombinant therapies are derived from blood however, these products are highly processed and not manufactured by local blood banks. Upon consultation with our clinical advisors, we have determined that these products do not have the same access and safety concerns as other blood and blood products. Thus, it is reasonable for us to distinguish these products from other blood and blood products. For the purposes of OPPS, we will not consider any plasma-derived products and their recombinant analogs, including albumin and immune globulins and except for hemophilia clotting factors, to fall under the category of ''blood and blood products''. Accordingly, we apply to these products the same packaging procedures applicable to other drugs and biologicals.

Vaccines Covered Under a Benefit Other Than OPPS

Outpatient hospital departments administer large numbers of the vaccines for influenza (flu), pneumococcal pneumonia (PPV), and hepatitis B, typically by participating in immunization programs encouraged by the Secretary because these vaccinations greatly reduce death and illness in vulnerable populations. In recent years, the availability and cost of the vaccines (particularly the flu vaccine) have varied considerably. We want to avoid creating any disincentives to provide these important preventative services that might result from packaging their costs into those of primary procedures, visits, or administration codes. Therefore, we proposed to pay for these vaccines under OPPS through the establishment of separate APCs.

We received no comments on our proposal to pay for these vaccines under separate APCs. However, we have had considerable discussion with providers in the past about the cost to hospitals of influenza and pneumococcal pneumonia vaccines in particular. In particular, we have had many discussions in which we were advised by providers that OPPS payment was insufficient for them to be able to guarantee that they would be able to offer these important vaccines to Medicare patients they treat. They cited the timing of updates to OPPS rates as well as volatility of costs as a result of irregular supplies of these vaccines as their major concern. Public health officials encourage high risk individuals, including Medicare beneficiaries, to receive flu immunitions beginning each September. Each flu season, a new vaccine is produced; the cost of the vaccine is also typically higher than the previous year's vaccine cost. Thus, from September through December, providers paid under the OPPS for administering flu vaccines do not receive the benefit of the update that occurs in January. In recent years, the cost of the vaccine has been volatile because of irregular supplies.

Therefore, we have decided to pay hospitals for influenza and pneumococcal pneumonia vaccines under reasonable cost methodology. Section 1833(t)(2)(A)(i) of the Act gives the Secretary discretion to define outpatient hospital services for purposes of payment under the OPPS. Until now we have defined it to include influenza and pneumococcal pneumonia vaccines. However, in view of the importance of these vaccines to the public health and our strong desire to ensure that hospitals are paid appropriately for these vaccines, we have decided to exclude them from OPPS.

We are therefore revising regulations at § 419.21(d)(3) to remove the words ''influenza'' and ''pneumococcal pneumonia.'' As a result of this change, hospitals, HHAs and hospices which were paid for these vaccines under OPPS will be paid reasonable cost for these vaccines. We will issue further instructions regarding how CORFs will be paid for these vaccines in 2003 and will issue implementation instructions for hospitals, HHAs and hospices.

Higher Cost Drugs

While our preferred policy is to package the cost of drugs and other items into the cost of the procedures with which they are associated, we are concerned that beneficiary access to care may be affected by packaging certain higher cost drugs. For this reason, we proposed to allow payment under separate APCs for high cost drugs for an additional year while we further study various payment options. Specifically, we proposed to pay separately for drugs for which the median cost per line (cost per unit multiplied by the number of units billed on the claim) exceeded $150, as we briefly describe below. We provide more detail in the proposed rule regarding the methodology we used to determine this threshold (67 FR 52124–52125).

To establish a reasonable threshold for determining which drugs we would pay under separate APCs rather than through packaging, we calculated the median cost per unit using 2001 claims data for each of the drugs for which transitional pass-through payment ceases January 1, 2003 and for those additional drugs that we have paid separately (status indicator ''K'') since the outset of OPPS.

We excluded from these calculations the orphan drugs, vaccines, and blood and blood products discussed above. Because many drugs are used and billed in multiple unit doses, we then multiplied the median cost per unit for the drug by the average number of units that were billed per line. Once we calculated an approximate median cost per line for the drug, we then arrayed the median cost per line in ascending order and examined the distribution. A natural break occurs at $150 per line, the midpoint of a $10 span between the drug immediately above and below the $150 point. Within the array, approximately 61 percent of the drugs fall below the $150 point and 39 percent of the array are above the point. Among the drugs that we proposed to package are some radiopharmaceuticals, vaccines, anesthetics, and anticancer agents. After including the costs of packaged drugs in the services with which they were provided, we noted that the median costs of those services increased. We solicited comments that address specific alternative protocols we might use when several packaged drugs whose total cost significantly exceeds the applicable APC payment amount may be administered to a patient on the same day (for example, multiple agent cancer chemotherapy).

We requested comments on the factors we considered in determining which drugs to package in 2003. We were particularly interested in comments for the exclusion of high cost drugs from packaging. We added that we would continue to analyze the effect

of our drug-packaging proposal to assess whether the $150 threshold should be adjusted to avoid significant overpayments or underpayments for the base APCs relative to the median costs of the individual drugs packaged into the APCs. Depending on this analysis, we stated that we may revise our threshold or criteria for packaging in the final rule for 2003. We expect to further consider each of these exclusions for packaging when we develop our proposals for the 2004 OPPS.

Although we expect to expand packaging of drugs to package payment for more drugs into the APC for the services with which they are billed, we nonetheless, requested comments on alternatives to packaging. One example of an alternative approach is to use different criteria from those we propose in this proposed rule to identify the drugs to package into procedure APCs and the drugs to pay separately. Another alternative approach would be to create APCs for groups of drugs based on their costs. Still another approach would be to create separate APCs for each drug. We emphasized in the proposed rule that we welcomed a full discussion of the alternatives as we determine the best way to ensure that hospitals are paid appropriately for the drugs they administer to the Medicare beneficiaries whom they treat in their outpatient departments.

Drugs that we pay for separately in 2003 are designated in Addendum B by status indicator ''K'' or ''G.''

A summary of the comments we received on this proposal and our responses to them are summarized below.

Comment: Numerous national trade associations, drug manufacturers, consultants, and other commenters opposed our proposal to package sunsetting drugs and biologicals that fell below a threshold of $150 median cost per line into procedure APCs. These commenters urged us to continue to pay separately for drugs and biologicals that were paid separately in 2002, including those for which pass-through status has expired. Some recommended that we maintain the 2002 payment levels until more accurate data could be obtained.

In contrast, one national hospital organization recommended that we adopt a much higher threshold of $1,000 for a drug to warrant separate payment and package all other drugs that fall below the threshold. Furthermore, another national hospital association encouraged us to expeditiously incorporate into APCs both low and high cost drugs that will lose their eligibility for transitional pass-through payments, while limiting separate APC payment only to orphan drugs, blood and blood products, certain vaccines and extremely costly drugs. The commenter also stated that integrating payments for packaged services will be less burdensome for hospitals and will eliminate incentives for higher costs that might be created by special additional reimbursement. As noted in section XI, the Medicare Payment Advisory Committee also urged CMS to incorporate more drugs into the base APCs.

Response: We appreciate all of the comments regarding the various aspects we should consider in making our decision to package lower-cost drugs and biologicals into procedure APCs. After carefully considering all recommendations submitted by the commenters regarding how we should treat these drugs and biologicals, we concluded that the packaging methodology we proposed is appropriate. We believe that we have sufficient data on drugs and biologicals to allow us to make a reasonable decision on whether to package individual items. We further believe that our decision to package these costs is consistent with the concept of a prospective payment system and we expect to continue incorporating additional drugs into the base APCs in future years.

Comment: Several commenters stated that the $150 threshold established for separate APC payment is arbitrary and such a packaging rule would create confusion among hospitals. One national hospital association was concerned that the policy would create incentives for pharmaceutical companies to increase their prices so their drugs will receive separate payment, and, potentially, for physicians to choose one drug over a clinically appropriate substitute.

Response: We acknowledge the concerns for using a median cost per line threshold level when the cost of a particular drug may fluctuate over time. However, we must set the rates prospectively. We will consider these issues further as we determine our policy for the criteria for packaging as we develop our proposed rule for the 2004 update.

Comment: Several commenters supported our decision to pay separately for higher-cost drugs, clotting factors, and orphan drugs in 2003, but recommended that we delay packaging higher-cost drugs until more accurate data is available. Other commenters suggested that we collect at least 2 more years of data on all drugs and biologicals before contemplating bundling them with other APCs. They stated that once a drug or biological is bundled, hospitals will have no incentive to code for it, and there will be no means of collecting data on the product in the future. Thus, by not packaging, we would be able to determine appropriate payment rates that reflect variations in hospital expenses for these products and continue to collect product-specific information.

Response: We agree with the commenters who stated that we should not package higher cost drugs until we have more data on those products; however, we disagree with the other commenters who suggested that we should not consider packaging any drugs and biologicals until we have collected data for two more years. We believe that at this time we have sufficient data to determine which drugs and biologicals should be packaged and which products we will pay separately for in 2003. While some hospitals may fail to separately report codes that represent packaged items, we have repeatedly instructed hospitals to submit all charges related to covered outpatient services, including those for packaged items. The total charges submitted by hospitals for each service will be used to set future rates. For that reason, and because of the possible impact on their ability to receive outlier payments for which they might qualify, it is extremely important that hospitals report all appropriate charges for their covered outpatient services.

Comment: Several commenters suggested that, at minimum, we should continue to pay separately for drugs and biologicals that typically cost more than $150 per administration, regardless of whether the median cost per line exceeds $150 using the 2001 claims data. In addition, a trade association suggested that we reflect the common practice of combining radiopharmaceuticals and others drugs used in performing nuclear medicine procedures by qualifying for separate payment those drug combinations which exceed the agency's $150 threshold.

Response: We appreciate the commenters' suggestions regarding methodologies that would refine the $150 threshold level used in making packaging determinations for 2003. We believe our proposed policy strikes a reasonable balance of simplicity, administrability, and responsiveness. We intend to review and refine our methodology in the future, and the proposals submitted by commenters will be taken into consideration at that time.

Comment: Several commenters claimed that our proposal to package many of the non-pass-through, lower cost drugs and biologicals with HCPCS codes for therapeutic administration is a violation of the ''two-times'' rule. Therefore, they recommended that we continue to pay for all drugs and biologicals separately or by revising the APCs in which the drugs are packaged.

Response: We do not agree with the commenters' assertion that packaging of drugs and biologicals results in violations of the two-times rule, stated in section 1833(t)(2) of the Act. We understand the commenters' confusion and attempt to provide a clarification on how we apply the ''two-times'' rule to determine APC structures. Most APC's consist of one or more services, which we refer to as ''procedures'' and code with CPT or HCPCS G codes, that are similar clinically and in terms of resource use. Many individual items (for example, sterile supplies or pharmaceuticals such as anesthetic agents) or ancillary services (for example, nursing or recovery room services) are integral to the procedure, and thus we have packaged them with the procedure. In some instances, such as APCs for transitional pass-through drugs and devices, the APC includes no procedure, and the APC is used only to pay for a specific item.

The ''two times'' rule requires that the highest median cost of a within an APC cannot be more than two times greater than the lowest median cost of a procedure within that APC. We apply the ''two-times'' rule to the total cost of each procedure (which includes items and services that are packaged within that procedure). In the case of APCs containing only items, we apply the rule to the cost of each item that is grouped in the APC. We do not apply the two times rule to the variation in cost of individual items or ancillary services we attribute to a single HCPCS code.

If we were to attempt to apply the rule to all items and ancillary services within the various procedures, accounting for the variation in cost of supplies such as bandages, reusable instruments, and other medical supplies would be a practical impossibility. It would lead to a highly fragmented set of payment cells and a greatly more complex payment system that would reduce the incentives for effective management by hospitals. We do not believe Congress would have intended such a result.

Consistent with the principles of prospective payment, we package the cost of as many items and ancillary services as possible into the median cost of a procedure. Therefore, our payment methodology for 2003, includes packaging the costs of drugs and biologicals with median costs below $150 per line into the costs of the procedures with which they were billed. We reviewed the median cost of the procedures used for administration of drugs and biologicals, before and after we packaged the costs of drugs and biologicals. Our review indicates that the final median cost appropriately accounts for the administration procedure and the cost of the administered drug and/or biologic.

Comment: A commenter requested that we include a statement in the final rule that was included in the preamble of the September 8, 1998 proposed rule (63 FR 47563–47564) that stated ''We propose to allow hospitals to provide drugs to patients without requiring that the hospital bill the patient, and without Medicare paying the hospital. Normally, hospitals are not allowed to waive such billing, since not charging a patient could be seen as an inducement to the patient to use other services at the hospital, for which the hospital would be paid. However, if the benefit is not advertised, we believe that provision of the self-administered drugs at no charge to the beneficiary need not constitute an inducement in violation of the anti-kickback rules. The hospital may not advertise this to the public or in any other way induce patients to use the hospital's service in return for forgoing payment.''

Response: We are not making final the proposal in the September 8, 1998 rule (63 FR 47563–64) that the commenter quotes. Medicare policy affecting how payment is made under the OPPS has evolved considerably since that rule. In the intervening years, CMS, providers, contractors, and beneficiaries all have acquired considerable experience under the OPPS that has added perspective and substance to a broad range of policy issues, including what is and is not payable under the OPPS. The following points summarize our current policy related to the issue posed by the commenter:

- In accordance with the in section 1861(s)(2)(B) of the Act and related Medicare regulations and program issuances, drugs and biologicals that are not usually self-administered by the patient are payable under the OPPS. As we explain elsewhere in this final rule, Medicare makes separate payment for certain drugs and biologicals and packages payment for others into the procedure with which they are billed.
- The fact that a drug has a HCPCS code and a payment rate under the OPPS does not imply that the drug is covered by the Medicare program, but only indicates how the drug may be paid if it is covered by the program.
- A code and payment amount does not represent a determination that the Medicare program covers a drug. Contractors must determine whether the drug meets all program requirements for coverage; for example, that the drug is reasonable and necessary to treat the beneficiary's condition and whether it is excluded from payment because it is usually self-administered.
- Certain drugs are so integral to a treatment or procedure that the treatment or procedure could not be performed without them. Because such drugs are so clearly an integral component part of the procedure or treatment, they are packaged as supplies under the OPPS into the APC for the procedure or treatment. Consequently, payment for them is included in the APC payment for the procedure or treatment of which they are an integral part.
- Under the OPPS, hospitals may not separately bill beneficiaries for items whose costs are packaged into the APC payment for the procedure with which they are used (except for the copayment that applies to the APC).

In short, neither the OPPS nor other Medicare reimbursement rules regulate the provision or billing by hospitals of non-covered drugs to Medicare beneficiaries. Accordingly, it would be inappropriate to include the statement in the 1998 rule. However, in some circumstances, such practices potentially implicate other statutory and regulatory provisions, including the prohibition on inducements to beneficiaries, section 1128A(a)(5) of the Act, or the anti-kickback statute, section 1128B(b) of the Act.

E. Expiration of Transitional Pass-Through Payments in Calendar Year 2003 for Brachytherapy

Section 1833(t)(6) of the Act requires us to establish transitional pass-through payments for devices of brachytherapy. As of August 1, 2000, we established item-specific device codes including codes for brachytherapy seeds, needles, and catheters. Effective April 1, 2001, we established category codes for brachytherapy seeds on a per seed basis (one for each isotope), brachytherapy needles on a per needle basis, and brachytherapy catheters on a per catheter basis. Because initial payment was made for a device in each of these categories in August 2000, we proposed that these categories (and the transitional pass-through payments) will be discontinued as of January 1, 2003. Furthermore, as discussed above, we

proposed that there will be no grace period for billing these category codes.

We received comments, both in writing and at the April 2002 Town Hall meeting, recommending that we continue to make separate payment for brachytherapy seeds. The basis for this recommendation is that the number of brachytherapy seeds implanted per procedure is variable. These commenters stated that the number and type of seeds implanted in a given patient depends on the type of tumor, its size, extent, and biology, and the amount of radioactivity contained in each seed. To further complicate the matter, the HCPCS codes used to report implantation of brachytherapy seeds are not tumor-specific. Instead, they are defined based on the number of sources, that is, the number of seeds or ribbons used in the procedure. This means that the treatment of many different tumors requiring implantation of widely varying numbers of seeds is described by a single HCPCS code. Therefore, it has been argued that given the costs of seeds and the variety of treatments described by a single HCPCS code, the cost of brachytherapy billed under a single HCPCS code could vary by as much as $3,000.

In determining whether to package seeds into their associated procedures, we considered all these factors as well as our claims data. Consistent with our proposed policy for other device costs and the cost of many drugs, as well as with the principles of a prospective payment system, our preferred policy is to package the cost of brachytherapy devices into their associated procedures. For 2003, in the case of remote afterloading high intensity brachytherapy and prostate brachytherapy, which we discuss below, weproposed to package the costs into payment for the procedures with which they are billed.

For other uses of brachytherapy, we proposed to defer packaging of brachytherapy seeds for at least 1 year. In those cases, when paying separately in 2003 for brachytherapy seeds, we proposed to continue payment on a per seed basis. The payment amount would be based on the median cost of brachytherapy seeds, per seed, as determined from our claims data.

We solicited comments on methodologies we might use to package all brachytherapy seeds beginning in CY 2004. For example, creation of tumor-specific brachytherapy HCPCS codes would reduce the variability in seed implantation costs associated with the current HCPCS codes used for seed implantation.

As stated above, beginning January 1, 2003, we proposed to package payment for brachytherapy seeds into the payment for the following two types of brachytherapy services:

Remote Afterloading High Intensity Brachytherapy

Participants in the April 5, 2002 Town Hall meeting expressed concern about packaging single use brachytherapy seeds into payment for procedures.

Remote afterloading high intensity brachytherapy treatment does not involve implantation of seeds. Instead, it utilizes a single radioactive ''source'' of high dose iridium with a 90-day life span. This single source is purchased and used multiple times in multiple patients over its life. One or more temporary catheters are inserted into the area requiring treatment, and the radioactive source is briefly inserted into each catheter and then removed. Because the source never comes in direct contact with the patient, it may be used for multiple patients. We note that the cost of the radioactive source, per procedure, is the same irrespective of how many catheters are inserted into the patient. We believe that the costs of this type of source should be amortized over the life of the source. Therefore, each hospital administering this type of therapy should include its own charge for the radiation source in the charge for the procedure. Therefore, we proposed to package the costs associated with high dose iridium into the HCPCS codes used to describe this procedure. Those codes are: 77781, 77782, 77783, and 77784.

Prostate Brachytherapy

The preponderance of brachytherapy claims under OPPS to date is for prostate brachytherapy. Brachytherapy is administered in several other organ systems, but the claims volume for non-prostate brachytherapy is very small, and hence our base of information on which to make payment decisions is slim. Furthermore, prostate brachytherapy uses only two isotopes, which are similar in cost, while brachytherapy on other organs involves a variety of isotopes with greater variation in cost. Consequently, we believe it would be prudent to wait for further experience to develop before proceeding to package non-prostate brachytherapy seeds.

A number of commenters at the April 5, 2002, Town Hall Meeting and elsewhere have stressed to us their views that brachytherapy seeds should remain unpackaged. The principle argument put forth in favor of this approach is that the number of seeds used is highly variable across patients. We do not find this argument compelling. Payments in the OPPS, as in other prospective payment systems, are based on averages. We believe the service volume at hospitals providing prostate brachytherapy is likely to be large enough for a payment reflecting average use of seeds to be appropriate.

Additionally, appropriate payment for prostate brachytherapy has been of concern to many commenters since implementation of the OPPS because facilities must use multiple HCPCS codes on a single claim to accurately describe the entire procedure. Because we determine APC relative weights using single procedure claims, commenters have argued that payments for prostate brachytherapy are, in part, based on error claims, resulting in underpayment for this important service. We agree that basing the relative weights for APCs reported for prostate brachytherapy services on only the small number of claims related to this service that are single procedure claims may be problematic. To increase the number of claims we could use to develop the proposed 2003 relative payment weights for prostate brachytherapy, we began by identifying all claims billed in 2001 for prostate brachytherapy. Unfortunately, closer analysis of these claims revealed that hospitals do not report prostate brachytherapy using a uniform combination of codes. Of the more than 12,000 claims for prostate brachytherapy that we identified in the 2001 claims data, no single combination of HCPCS codes occurred more than 25 times.

Therefore, in order to facilitate tracking of this service, we proposed to establish a G code for hospital use only that will specifically identify prostate brachytherapy. We proposed as the descriptor for this G code the following: ''Prostate brachytherapy, including transperineal placement of needles or catheters into the prostate, cystoscopy, and interstitial radiation source application.'' This G code would be used by hospitals instead of HCPCS codes 55859 and 77778 to bill for prostate brachytherapy. Hospitals would continue to use HCPCS codes 55859 and 77778 when reporting services other than prostate brachytherapy. We would also instruct hospitals to continue to report separately other services provided in conjunction with prostate brachytherapy, such as dosimetry and ultrasound guidance. These additional services would be paid according to the APC payment rate established by our usual methodology.

This G code will allow us to package brachytherapy seeds into the procedures for administering prostate brachytherapy while permitting us to pay separately for brachytherapy seeds which are administered for other procedures. Therefore, we proposed to package the costs of the brachytherapy seeds, catheters, and needles into the payment for the prostate brachytherapy G code. In order to develop a payment amount for this G code, we used all claims where both HCPCS codes 55859 and 77778 appeared. We packaged all revenue centers and appropriate HCPCS codes, that is, HCPCS with status indicator ''N.'' We then determined median costs of the line items for HCPCS codes 55859 and 77778 and added the two. Next, we packaged the costs of all C codes, whether an item-specific or a device category code, into the payment amount. We proposed to assign APC 0684 with status indicator ''T.'' We believe the payment rate proposed for this G code appropriately reflects the costs of the procedures, the brachytherapy seeds, and any other devices associated with these procedures. We solicited comments on this proposal.

Packaging of Other Device Costs Associated With Brachytherapy

We proposed to package the costs of brachytherapy needles and catheters with whichever procedures they are reported, similar to our proposal for packaging the costs of other devices that will no longer be eligible for a transitional pass-through payment in 2003. Because the HCPCS code descriptors for brachytherapy are based on the number of catheters or needles used, we believe the costs of these devices would be appropriately reflected within the costs of the associated procedure.

Brachytherapy

Comment: One commenter believed that assigning CPT Code 77799 to APC 313 was inappropriate because it was the highest paying brachytherapy APC and it violated the two times rule.

Response: We thank the commenter for bringing this to our attention. The CPT code 77799 should be assigned to APC 312, the lowest paying brachytherapy APC, which is consistent with our policy of assigning unspecified codes to the lowest paying similar APC because we do not know what procedures are being performed. However, we do not apply the two times rule to unspecified codes like 77799 for that same reason. We are assigning 77799 to APC 312.

Comment: Several commenters were concerned that the proposed payment rates for APCs 1718, for iodine seeds, and 1720, for palladium seeds were significantly lower than the 2002 payment rates for these brachytherapy sources. The commenters stated that the new rates do not reflect hospital acquisition costs and recommended that we continue pass-through status for these seeds in 2003 or refine the claims data used to set payment rates.

Response: Our payment rates for 1718 and 1720 are based on the median costs for these seeds in our 2001 claims data. We are confident that these data reflect actual hospital acquisition costs. By statutory mandate, the OPPS system, in aggregate, does not pay hospitals full costs for services. Therefore, it should not be expected that payment rates (which involve turning median costs into relative weights and applying scaling factors) will always reflect 100 percent of hospital acquisition cost.

Comment: Several commenters urged us to identify all sources currently used in brachytherapy and cover those sources on an interim basis. They suggested we retain a C code for ''unlisted'' brachytherapy sources to allow hospitals to bill for sources not on the current pass through list.

Response: We only create C codes for items based on formal applications for a specific device. We do not create C codes for unlisted devices. Interested parties may submit an application for a pass through device using the process described in the April 7, 2000 final rule (65 FR 18481–18482).

Comment: A commenter suggested continuing the pass-through categories for brachytherapy seeds, needles, and catheters for one year in order to collect more data.

Response: Statutory provisions preclude us from continuing these categories for an additional year.

Comment: One commenter asked us to refer to brachytherapy ''sources'' instead of brachytherapy ''seeds.''

Response: We agree and will do so.

Comment: One commenter responded to our solicitation of comments regarding the advisability of creating tumor specific brachytherapy HCPCS codes in the future. The commenter did not favor this idea because of the variability in number and type of brachytherapy devices used to treat a single disease. Additionally, it would create an overly complex coding system.

Response: We thank the commenter and are continuing to review this issue.

Comment: Several commenters were concerned about the proposed payment reduction for APC 313 (High Dose Afterloading Brachytherapy). The commenters stated that hospitals were coding incorrectly for these services because many claims did not use C codes for the sources or catheters. Therefore, our data did not reflect actual hospital costs. The commenters recommended that we increase the payment rate, use only claims that were correctly coded, or continue to pay separately for the sources.

Response: As described elsewhere in this rule, we have taken steps to mitigate the severe payment decreases that were proposed for several APCs including APC 313. Therefore the final payment rate for APC 313 will be higher than the proposed payment rate. We will continue to review the issues raised by the commenters. It is unclear how we should address the issue of coding for APC 313 because high dose brachytherapy sources are reusable whose costs must be amortized per use over a 90 day period. Furthermore, hospitals have been using these sources for many years; therefore, we would expect their charges would reflect this amortized cost even in the absence of using a C code. Additionally, it is likely we over estimated device costs for this APC because of the methodology we used for folding in device costs insetting 2002 payment rates. Lastly, we are unable to continue pass-through payments for devices used in APC 313 and do not think it is appropriate to pay separately for high dose brachytherapy sources for the reasons discussed.

Comment: Several commenters were concerned about the ''N'' status indicator assigned to Yttrium-90 brachytherapy sources. They stated that it is an implantable seed used in treating liver cancer. They also claimed that its median cost was much higher than the cost reflected in our claims data.

Response: We will place Yttrium-90 in an APC. Assigning status indicator ''N'' was an error. We will use our claims data to set the payment rate. We will continue to review our claims data and external data sources as we update the payment rate in 2004.

Comment: Several commenters suggested that we create HCPCS codes and APCs for high dose implantable brachytherapy sources. They explained that sources such as iodine-125 and palladium-103 may be ''high'' intensity or 'low'' intensity (that is, emit different amounts of radiation) and that our payment for these sources account for the cost variation associated with sources of different intensities. Another commenter requested that we create three levels of APCs for brachytherapy needles and catheters to account for cost variation of those devices. Lastly, another commenter suggested we create

three APCs to reflect levels of seed utilization (for example, simple for less than 85 seeds, intermediate for 85–99 seeds and complex for more than 100 seeds).

Response: We disagree. Our median cost data should reflect the cost variation among seeds of different intensity. For example if low intensity seeds cost $40 and are used 80 percent of the time, and high intensity seeds cost $50 and are used 20 percent of the time, then our cost data should reflect a cost of $42 per seed. Insofar as no hospital specializes in administering high intensity seeds, on average, hospitals should be paid appropriately for both types of seeds. Furthermore it would be administratively burdensome and make accurate coding very difficult, if we created APCs for every variation in seeds. We believe devices other than seeds should be packaged into procedure APCs, as we have done with all other devices. Because we pay for sources on a ''per seed'' basis there is no reason to create APCs for simple, intermediate, and complex seed utilization.

Comment: One commenter requested that we set up a system to account for the variability in use of brachytherapy devices. Another commenter said that brachytherapy codes were not well understood so all supplies and sources should be paid separately.

Response: We disagree and are finalizing our proposal to package all devices except for seeds in cases of non-prostate cancer brachytherapy. Doing what the commenters requested would create an extremely burdensome system with no discernable benefit.

Comment: Many commenters disagreed with our proposal to create a G code describing prostate brachytherapy with packaged implantable sources, needles, and catheters. They cited the following as reasons:

- The high variability in the number of sources used per treatment.
- The difference in cost between iodine and palladium seeds.
- Packaging of seeds violates the two times rule.
- Some hospitals specialize in complex cases requiring high numbers of seeds and would always be underpaid.
- A single payment rate would provide incentives to use cheaper (iodine) seeds when more expensive seeds (palladium) were clinically appropriate.
- A single payment rate would provide an incentive to use fewer, higher activity seeds even if use of more lower activity seeds was clinically appropriate.
- Underpayment for prostate brachytherapy will create an incentive to use more invasive, riskier, and costly treatments for prostate cancer.
- The proposed payment rate is too low as a result of using improperly coded claims.
- Creating a new G code is administratively burdensome.

Most commenters recommended that we continue to pay separately for brachytherapy sources used for prostate cancer, as we proposed to do for other forms of cancer. Some commenters requested that we withdraw our proposal for the G code describing brachytherapy and continue to recognize CPT codes 55859 and 77778 while other commenters agreed with our proposal to create the G code with packaged needles and catheters but asked that we not package brachytherapy sources into it. Some commenters requested that, if we finalize our G code, that it be paid as least as much as combined payment rate for the APCs containing CPT codes 55859 and 77778.

A few commenters agreed with our proposed G code approach but asked that we create 2 G codes, one for prostate brachytherapy using iodine seeds and another for prostate brachytherapy using palladium seeds. They also suggested that if CMS finalizes one or more G codes, coding edits should be developed to ensure proper coding of these procedures.

Response: We thank all the commenters. After review of all the comments we have decided to create 2 G codes describing prostate brachytherapy. G0256, Prostate brachytherapy using permanently implanted palladium seeds, including transperitoneal placement of needles or catheters into the prostate, cystoscopy and application of permanent interstitial radiation source, and G0261, Prostate brachytherapy using permanently implanted iodine seeds, including transperitoneal placement of needles or catheters into the prostate, cystoscopy and application of permanent interstitial radiation source. These codes package the costs of needles, catheters, and sources. In developing payment rates for these codes we used only correctly coded claims. For example, for G0256 we used only claims that included CPT codes 55859, 77778, and a C code for palladium sources. We did not use any claims where there was no C code for a brachytherapy source or a claim where there were C codes for more than one source (for example, palladium and iodine sources). Analysis of the claims we used in setting payment rates revealed that the median number of seeds packaged into both codes is 85. We believe that the median costs of these codes reflect the resources required to perform these procedures.

We believe that implementation of these G codes should address the clinical concerns of the commenters. We do not believe these codes will create an incentive to use one type of source rather than another. Additionally, because of the number of seeds packaged we do not believe there will be an incentive to use fewer seeds inappropriately. Furthermore, we believe the number of packaged seeds addresses the concerns about seed variability as we are not aware of facilities that specialize in using more palladium or iodine than are packaged in these codes. Finally, we do not have evidence that implementation of these G codes and their payment rates will create an incentive to treat prostate cancer with more invasive, more costly treatments.

For non-clinical concerns, we think that implementation of the G codes will actually decrease administrative burden as it will now be easier for hospitals to properly code for prostate brachytherapy procedures, and we believe that the methodology we used to develop median costs addresses the concerns about underpayment.

When performing prostate brachytherapy hospitals should use G0256 and G0261 and should not report CPT codes 55859 and 77778. Furthermore hospitals should not report the APCs for iodine and palladium brachytherapy sources. CMS will create edits to prevent billing of these items and services with prostate brachytherapy. However, other services provided during the provision of prostate brachytherapy such as intraoperative ultrasound, dosimetry, etc., are separately payable and should be reported on the claim if performed.

F. Payment for Transitional Pass-Through Drugs and Biologicals for Calendar Year 2003

As discussed in the November 13, 2000 interim final rule (65 FR 67809) and the November 30, 2001 final rule (66 FR 59895), we update the payment rates for pass-through drugs on an annual basis. Therefore, as we have done for prior updates, we proposed to update the APC rates for drugs that are eligible for pass-through payments in 2003 using the most recent version of the Red Book, the July 2002 version in this case. The updated rates effective January 1, 2003 would remain in effect until we implement the next annual

update in 2004, when we would again update the AWPs for any pass-through drugs based on the latest quarterly version of the Red Book. This retains the update of pass-through drug prices on the same calendar year schedule as the other annual OPPS updates.

As described in our final rule of November 30, 2001 (66 FR 59894), in order to establish the applicable beneficiary copayment amount and the pass-through payment amount, we must determine the cost of the pass-through eligible drug or biological that would have been included in the payment rate for its associated APC had the drug or biological been packaged. We used hospital acquisition costs as a proxy for the amount that would have been packaged, based on data from an external survey of hospital drug costs (see the April 7, 2000 final rule (65 FR 18481)). That survey concluded that—

- For drugs available through only one source drugs, the ratio of acquisition cost to AWP equals 0.68;
- For multisource drugs, the ratio of acquisition cost to AWP equals 0.61;
- For drugs with generic competitors, the ratio is 0.43.

As we stated in our final rule of November 30, 2001 (66 FR 59896), we considered the use of the study-derived ratios of drug costs to AWP to be an interim measure until we could obtain data on hospital costs from claims. We stated that we anticipated having this data to use in setting payment rates for 2003.

As described elsewhere in this preamble, we used 2001 claims data to calculate a median cost per unit of drug for each drug for which we are currently paying separately. We compared the median per unit cost of each drug to the AWP to determine a ratio of acquisition cost to AWP. Using the total units billed for each drug, we then calculated a weighted average for each of the above three categories of drugs. These calculations resulted in the following weighted average ratios:

- For sole-source drugs, the ratio of cost to AWP equals 71.0 percent.
- For multisource drugs, the ratio of cost to AWP equals 68.0 percent.
- For drugs with generic competitors, the ratio of cost to AWP equals 46.0 percent.

We proposed to use these percentages for determining the applicable beneficiary copayment amount and the pass-through payment amount for most drugs eligible for pass-through payment in 2003. However some drugs may fall into two other classes. The first class includes a drug that is new and for which no cost is yet included in an associated APC. For such a drug, because there is no cost for the drug yet included in an associated APC, the pass-through amount will be 95 percent of the AWP and there would be no copayment. The second class includes a drug that is new and is a substitute for only one drug that is recognized in the OPPS through an unpackaged APC. For drugs in this second class, the pass-through amount would be the difference between 95 percent of the AWP for the pass-through drug and the payment rate for the comparable dose of the associated drug's APC. The copayment would be based on the payment rate of its associated APC. We believe that using this methodology will yield a more accurate payment rate.

We have received questions for our definition of multisource drugs. In determining whether a drug is available from multiple sources, we consider repackagers to be among the sources. This is consistent with the findings of the survey cited above which indicated a lower ratio of acquisition cost to AWP from multiple sources including repackagers.

We note that determining that a drug is eligible for a pass-through payment or assigning a status indicator ''K'' to a drug or biological (indicating that the drugs or biologicals is paid based on a separate APC rate) indicates only the method by which the drug or biological is paid if it is covered by the Medicare program. It does not represent a determination that the drug is covered by the Medicare program. For example, Medicare contractors must determine whether the drug or biological is: (1) Reasonable and necessary to treat the beneficiary's conditions; and (2) excluded from payment because it is usually self-administered by the patient.

We received several comments on this proposal, which are summarized below.

Comment: A commenter stated that the payments for pass-through drugs were too generous compared to those for the devices.

Response: We calculated payments for pass-through drugs and devices in accordance with the statute in sections 1833(t)(6)(D)(i) and (ii) of the Act.

Comment: Numerous commenters were concerned with the time required to incorporate new drugs and biologicals into the APC system. Some commenters indicated that we frequently depart from our own timeframe of 4 to 7 months from the date of submission of an application to the potential effective data for pass-through status. Thus, they urged us to follow one of the following recommendations: Expedite the processing of pass-through applications and the creation of C codes; develop C codes for products pending FDA approval, or permit retroactive dates for new codes to allow for retroactive reimbursement for hospitals. Another commenter suggested that we create a centralized on-line listing of all current pass-through drugs, biologicals, and devices along with all of the new applications under review.

Response: We understand the commenters' concerns, and we would like to clarify the operation of our quarterly deadlines. We establish deadlines for submission of transitional pass-through applications that are 4 months in advance of the next quarterly update to the claims-payment system in order to accommodate time for review and decision and for revisions to the claims-payment systems. Thus an applicant submitting by the deadline can be assured we will consider the application for possible inclusion in the next quarterly update. However, we cannot guarantee that we will be able to make a decision regarding the application within that period of time. Incomplete applications or the need to answer technical questions that arise during review may extend the period of review.

We have instructed hospitals through our fiscal intermediaries that hospitals may bill for new drugs following FDA approval using an unspecified HCPCS code until a permanent HCPCS is established for the drug and/or we have approved pass-through payment for the drug. Payment for a new drug, if determined by the fiscal intermediary to be a covered drug, would be packaged. However inclusion of the drug charges for the procedure will be considered in determining outlier payments and will be used in future rate setting for the procedure and/or the drug once its pass-through status expires. Hospitals should note that we have lowered the threshold for outlier payments for 2003, and this new threshold requirement is described in section IX of the preamble.

We intend to minimize the delays in the review process as much as possible so that we can facilitate access to new products and services for our beneficiaries, which is why we review new pass-through applications on a quarterly basis. We disagree with the commenters who suggested that we allow retroactive reimbursement for hospitals to the date of FDA approval. Moving to such a policy would greatly increase the burden on our and hospitals' computer systems in programming, testing, and implementing updates to the payment system. We do not provide for retroactive changes in reimbursement because this is a prospectively

determined payment system and because retroactive payment rate changes are administratively burdensome and confusing for beneficiaries and providers.

We appreciate the suggestion to create an on-line listing of all transitional pass-through items and applications that are under review, and will consider it for the future.

Comment: Several national trade associations and drug companies were concerned with our proposal to consider drugs and biologicals that were subject to repackaging as multisource drugs. They indicated that repackagers do not manufacture the products; instead, they purchase the products from the manufacturers, package them differently, and then sell the products. The manufacturer of the product continues to be the sole source of the product; therefore, we should regard repackaged products as sole source drugs. Also, they recommended that we utilize the ''Orange Book'' to determine whether a drug should considered single source, multisource, or generic for OPPS purposes.

Response: We acknowledge that we treat certain drugs that have only one manufacturer as a multisource drug. Our rationale behind regarding a repackaged drug as a multisource product is that, even though there may be only one manufacturer of a repackaged drug, there is more than one party selling the repackaged drug in the market. Therefore, a repackager may charge a different price to hospitals for the same product sold by its manufacturer. Our intention in the payment system is to account for the economic relationship between market prices for repackagers, multisource drugs, and sole source drugs. From our analysis, we judged the drugs sold by repackagers to be similar to drugs available from more than one manufacturer in terms of price differentials and estimated hospital acquisition costs. We also note that if we were to recategorize these drugs as single source, we would have to recalculate the average values for acquisition costs for the three categories of drugs.

Comment: Several commenters suggested that we use the October 2002 Red Book information to set the final pass-through payment rates for 2003. Also, the commenters urged us to update the pass-through payment rates quarterly since there will be significantly fewer pass-through drugs in 2003.

Response: Upon considering the commenters' suggestions in using the October 2002 Red Book to set the pass-through payment rates for drugs and biologicals, we decided to continue using the July 2002 Red Book as we proposed since it is most consistent with our publication schedule. In the future, for all of our final rules that must be published by November, we will continue to use the July edition of the Red Book for that year.

We carefully considered the proposal to update the pass-through payments on a quarterly basis and decided to continue with only annual updates of the rates. From previous experience, we know that doing a quarterly update of the prices for all the pass-through drugs and biologicals would be burdensome on our contractors and disruptive to both our computer systems and pricing software. Although we make other updates on a quarterly basis, we do not include revision of rates in these updates unless an error was made in the calculation of the rate. We see no compelling reason to update the transitional pass-through drug prices under the OPPS more frequently than the other payment rates in the outpatient system.

Comment: Several commenters indicated that in the proposed rule we appeared intent on estimating pass-through expenditures that will exceed the statutory cap and trigger a pro-rata reduction of pass-through payments in 2003.

Response: Frankly, we find it puzzling that commenters would believe we would manipulate the estimates of pass-through spending with the intention of ensuring that a pro-rata reduction would be imposed. Our estimate of transitional pass-through spending indicates that no pro-rata reduction will be necessary in 2003.

Comment: A commenter urged us to develop a process for acknowledgement and payment adjustment when it is determined that the rates published in the Red Book are incorrect.

Response: As stated elsewhere in this final rule, we update payment rates for pass-through drugs and biologicals only on an annual basis using the information published in the July edition of the Red Book. We rely on information supplied by manufacturers to the Red Book to be accurate.

V. Criteria for New Device Categories As Implemented in the November 2, 2001 Interim Final Rule With Comment

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–113, amended section 1833(t) of the Act to make major changes that affected the new PPS for hospital outpatient services. Section 1833(t)(6) of the Act, which was added by section 201(b) of the BBRA, provided for temporary additional payments, referred to as ''transitional pass-through payments,'' for certain drugs, biologicals, and devices. Section 1833(t)(b) of the Act provided for payment of new medical devices, as well as new drugs and biologicals, in instances in which the item was not being paid as a hospital outpatient service as of December 31, 1996, and when the cost of the item is ''not insignificant'' in relation to the OPPS payment amount. Section 402 of BIPA, which amends section 1833(t)(6) of the Act, requires us to use categories in determining the eligibility of devices for transitional pass-through payments effective April 1, 2001. Section 1833(t)(6)(B)(ii)(IV) of the Act, as added by section 402(a) of BIPA, requires us to establish a new category for a medical device when—

- The cost of the device is not insignificant in relation to the OPPS payment amount;
- No existing or previously existing device category is appropriate for the device; and
- Payment was not being made for the device as an outpatient hospital service as of December 31, 1996. However, section 1833(t)(6)(B)(iv) of the Act, also added by section 402(a) of BIPA, provides that a medical device shall be treated as meeting the first and third requirements if either—
- The device is described by one of the initial categories established and in effect or
- The device is described by one of the additional categories we established and in effect, and—

—An application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved; or

—The device has been cleared for market under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or

—The device is exempt from the requirements of section 510(k) of the Federal Food, Drug, and Cosmetic Act under section 510(l) or section 510(m) of that Act.

Thus, otherwise covered devices that are described by a currently existing category may be eligible for transitional pass-through payments even if they were paid as part of an outpatient service as of December 31, 1996. At the same time, no categories will be created on the basis of devices that were paid on or before December 31, 1996.

Section 1833(t)(6)(B)(i)(I) of the Act, as amended by BIPA, required us to establish, by April 1, 2001, an initial set of categories based on device by type in such a way that specific devices eligible

for transitional pass-through payments under sections 1833(t)(A)(ii) and (iv) of the Act as of January 1, 2001 would be included in a category. We developed this initial set of categories in consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties, as required by section 1833(t)(6)(B)(i)(II) of the Act. We issued the list of initial categories on March 22, 2001, in Program Memorandum (PM) No. A–01–41. Subsequently, an additional two categories and clarifications of some of the categories' long descriptors were made. The latest PM that lists all the existing device categories (including three additional categories that became effective July 1, 2002) is Transmittal No. A–02–050, issued June 17, 2002, which can be accessed on our Web site, *http://cms.hhs.gov.*

Section 1833(t)(6)(B)(ii)(III) of the Act, as amended by BIPA, requires us to establish criteria by July 1, 2001 that will be used to create additional categories. Section 1833(t)(6)(B)(ii)(II) of the Act requires that no medical device is described by more than one category. In addition, the criteria must include a test of whether the average cost of devices that would be included in a category is ''not insignificant'' in relation to the APC payment amount for the associated service.

On November 2, 2001, we set forth in an interim final rule (66 FR 55850) the criteria for establishing new (that is, additional) categories of medical devices eligible for transitional pass-through payments under the OPPS as required by section 1833(t)(6)(B)(ii) of the Act. We received five comments regarding our criteria published in the November 2, 2001 interim final rule with comment period. We summarize and respond to these comments below.

A. Criteria for Eligibility for Pass-Through Payment of a Medical Device

As noted above, in our April 7, 2000 final rule with comment period (65 FR 18480), we defined new or innovative devices using eight criteria, three of which were revised in our August 3, 2000 interim final rule with comment period (65 FR 47673 through 47674). These criteria were set forth in regulations at § 419.43(e)(4). For the most part, these criteria remained applicable when defining a new category for devices. That is, devices to be included in a category must meet all previously established applicable criteria for a device eligible for transitional pass-through payments. The definition of an eligible device, however, needed to change to conform to the requirements of the amended section 1833(t)(6)(B)(ii) of the Act, that is, the requirement to establish additional categories, which we accomplished in our November 2, 2001 interim final rule.

In addition, we clarified our criterion that states that a device must be approved or cleared by the FDA. The approval or clearance criterion applies only if FDA approval or clearance is required for the device as specified at new § 419.66(b)(1). For example, a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with § 405.203 through § 405.207 and § 405.211 through § 405.215 is exempt from this requirement. A device that has received an FDA IDE and is classified by the FDA as a Category B device is eligible for a transitional pass-through payment if all other requirements are met.

B. Criteria for Establishing Additional Device Categories

As described above, in determining the criteria for establishing additional categories, section 1833(t)(6)(B)(ii) of the Act mandates that new categories must be established for devices that were not being paid for as an outpatient hospital service as of December 31, 1996, and for which no category in effect (or previously in effect) is appropriate in such a way that no device is described by more than one category and the average cost of devices to be included in a category is not insignificant in relation to the APC payment amount for the associated service. Based on these requirements, we announced in the November 2, 2001 interim final rule that we will use the following criteria to establish a category of devices:

- *Substantial clinical improvement.* The category describes devices that demonstrate a substantial improvement in medical benefits for Medicare beneficiaries compared to the benefits obtained by devices in previously established (that is, existing or previously existing) categories or other available treatments, as described in regulations at new § 419.66(c)(1).

We stated our belief that this criterion ensures that no existing or previously existing category contains devices that are substantially similar to the devices to be included in the new category. This criterion is consistent with the statutory mandate that no device is described by more than one category.

In addition, we said that this criterion limits the number of new categories, and consequently transitional pass-through payments, to those categories containing devices that offer the prospect of substantial clinical improvement in the care of Medicare beneficiaries. Section 1833(t)(6)(E)(iii) of the Act, requires that, if the Secretary estimates before the beginning of the year that the total estimated amount of pass-through payments would exceed a specified percentage of total program payments (2.5 percent before 2004 and no more than 2 percent thereafter), we must uniformly reduce (prospectively) each pass-through payment in that year by an amount adequate to ensure that the limit is not exceeded.

We established this criterion because it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less apparent. These devices can still be used by hospitals, and hospitals will be paid for them through the appropriate APC payment. To the extent these devices are used, the hospitals' charges for the associated procedures will reflect their use. We will use data on hospital charges to update the APC payment rates as part of the annual update cycle. Thus, the payment process will provide an avenue to reflect appropriate payments for devices that are not substantial improvements.

We are currently evaluating requests for a new category of devices against the following criteria in order to determine if it meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

—Reduced mortality rate with use of the device.

—Reduced rate of device-related complications.

—Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
—Decreased number of future hospitalizations or physician visits.
—More rapid beneficial resolution of the disease process treated because of the use of the device.
—Decreased pain, bleeding, or other quantifiable symptom.
—Reduced recovery time.

As part of the application process (described in section V.B.1 of this final rule), we require the requesting party to submit evidence that the category of devices meets one or more of these criteria. We noted that the requirements set forth above will be used only for determining whether a device is eligible for a new category under section 1833(t)(6)(B) of the Act, which authorizes transitional pass-through payments for categories of devices. These criteria are not intended for use in making coverage decisions under section 1862(a)(1)(A) of the Act. We noted that adoption of these criteria is consistent with the recommendation of the Medicare Payment Advisory Commission, in its March 2001 Report to Congress, that pass-through payments for specific technologies be made only when a technology is new or substantially improved.

We stated that we determine which devices represent a substantial clinical improvement over existing devices by using a panel of Federal clinical and other experts, supplemented if appropriate by individual consultation with outside experts. These decisions are, in general, based on information submitted by the requester about the clinical benefit of the devices as described in the above criteria, including, where available, evidence from clinical trials or other clinical investigations. A panel of clinical experts from CMS has thus far made all of our decisions on eligibility for an additional device category.

As indicated in the November 2, 2001 interim final rule, we believe that almost all substantial clinical improvements in technology that are appropriately paid for under the transitional pass-through provisions result in measurable improvements in care from the perspective of the beneficiary. Nevertheless, there may be some improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment (as opposed to packaged payments) even though they do not directly result in substantial clinical improvements. For example, improvements in such factors as the strength of materials, increased battery life, miniaturization, might so improve convenience, durability, ease of operation, etc., that such an improvement in medical technology might be considered as a separate factor from ''substantial clinical improvement'' in beneficiary care.

We invited public comment on this issue and particularly asked for examples of medical technologies for which pass-through payments might be appropriate even though they would not also pass a test based on substantial improvement in beneficiary outcomes. Although we received a number of comments on this criterion, only one attempted to provide an example of new medical technology that might not also pass a test based on substantial improvement in beneficiary outcomes. This example is described in our summary of comments and responses below.

As we noted in the November 2, 2001 interim final rule, we will continue to evaluate these criteria as we gain experience in applying them, and we will consider revisions and refinements to them over time as appropriate.

Comment: Most commenters expressed concerns regarding our criterion that new device categories demonstrate substantial clinical improvement to be eligible for pass-through payment. Device manufacturers and representatives felt that evidence of clinical outcomes should not be part of the device category evaluation and eligibility process. Some maintained that we already have standards for determining clinical benefit as part of the Medicare coverage process and we should not have such requirements in payment determination. One commenter claimed that we would be unable to determine substantial clinical improvement for pass-through categories separately from national coverage decisions, since we will be reviewing the same types of evidence for both processes. This commenter held that a payment policy decision using clinical improvement criteria is a de facto coverage decision that our Coverage Analysis Group and carriers would feel compelled to go along with.

One device manufacturer was concerned that any employment of inappropriate evidentiary standards in evaluating improvement in diagnosis or treatment when applying this criterion could be a barrier to pass-through payment for some new technologies.

Yet, some manufacturers agree that pass-through payment should be limited to technologies that represent significant advancements in providing beneficial new therapy options. A number of commenters felt we should take into account improvements in devices' technology per se, for example, material, power source, size, etc., and not limit our criterion of improvement to clinical improvement. Some commenters held that only technological aspects of new medical devices should be analyzed to determine whether there are advancements over existing pass-through devices to determine whether a device should be considered for an additional category. A manufacturer stated that if we feel that a criterion based on clinical benefits is needed, we should employ a ''substantially different'' criterion to determine eligibility for a new category. Under this suggestion, any difference in therapeutic effect, indication, surgical approach, safety or side effects, mechanics or function that offers a ''new beneficial therapeutic alternative'' would be considered ''substantial.''

One manufacturer also stated that a ''substantial clinical improvement'' criterion may be unnecessary, because we already have a criterion that addresses costs that are ''not insignificant.''

Response: Although the information required for pass-through category applications is similar for coverage determinations, the information is used differently. The purpose of the ''reasonable and necessary'' condition in evaluating coverage is different than the OPPS purpose of determining appropriate pass-through payment for new technology items. We are not attempting to determine coverage under the OPPS, only whether a payment under the pass-through mechanism is warranted. We adopted the ''substantial clinical improvement'' criterion to help us identify those devices that are not adequately described by any previously established device categories.

Those who argue that we should employ a ''substantially different'' or a ''clinical benefit'' criterion rather than the ''substantial clinical improvement'' do not answer the question as to how different a new technology should be to be considered eligible for a new device category. It seems to us that many of the differences listed in the suggestion to base a criterion on ''substantial differences'' noted above may not reflect qualitatively meaningful differences and such devices could be adequately described by the existing or previously existing categories. If a new device technology were adequately described by a category of devices in terms of its clinical application and benefits, then an additional category would not seem

warranted. Still, as we have stated in the November 2, 2001 interim final rule and again above, there may be some improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment even though they do not directly result in substantial clinical improvements. We will continue to allow the flexibility in our evaluation process to consider such items for new categories.

We believe it is harder to make a determination of substantial difference than it is to make a determination as to substantial clinical benefit. Furthermore, we believe that, in general, transitional pass through payments should be made only for technologies that benefit beneficiaries beyond the technologies currently available.''

We believe it is harder to make a determination of substantial difference than it is to make a determination as to substantial clinical benefit. Furthermore, we believe that, in general, transitional pass-through payments should be made only for technologies that benefit beneficiaries beyond the technologies currently available.

The notion that a ''substantial clinical improvement'' criterion may be unnecessary, because we already have a criterion that addresses ''not insignificant cost,'' is misplaced. The cost of the new technology may or may not directly address a nominated device's clinical benefits. Payment for a costly device may be related to a number of factors, such as Medicare payment policy for a technology or the cost of raw materials or manufacturing process, irrespective of substantial clinical improvement. We established the clinical improvement criterion in addition to the cost significance criterion mandated under statute because one cannot accurately infer that a high relative cost is indicative that a device cannot be described by an existing or previous category of devices. Nor can we automatically infer that a substantially clinically improved device necessarily bears significantly higher cost than what we are currently paying for pass-through devices and procedural payments through the APC payment rates. Therefore, both criteria are needed.

Comment: In the November 2, 2001 interim final rule, we invited public comment on the issue of substantial improvement, saying we would be interested in examples of medical technologies for which pass-through payments might be appropriate even though they would not pass a test based on substantial improvement in clinical outcomes. Several commenters pointed to differences in brachytherapy devices as examples. These commenters said that differences in devices should be reflected by establishing separate device categories by: different chemical substances/radioisotope, therapeutic radiation activity levels, implantation arrays of brachytherapy devices, and mechanisms of injecting brachytherapy devices that improve safety and function.

Response: We have reviewed many applications for brachytherapy devices and believe that there is a congruence between new technologies that might be eligible for transitional pass-through payments in the absence of producing substantial clinical benefit and new technologies that do produce substantial clinical benefit.

Comment: Commenters requested that we clarify the process that is employed by Federal and external experts to evaluate substantial clinical improvement on the part of nominated devices. One commenter expressed concern that a Federal panel of experts may slow down decision-making and suggested a flexible process in reviewing category applications. The commenter suggested that we rely on our internal clinical staff to make decisions not requiring outside assistance. The commenter also suggested that our review process should be open and allow the manufacturer the opportunity to present information to the panel. The list of panelists, agendas, proceedings and decisions should be made public.

Response: Our panel consists of CMS clinical experts. We consult with outside experts as appropriate. We believe that this process results in making appropriate, timely decisions while allowing for maximum flexibility. Public meetings would inevitably slow the process. We give ample opportunity for manufacturers to provide information, and we frequently meet with manufacturers to discuss their applications.

Comment: One commenter felt that the language of the statute does not support our criterion that devices show evidence of substantial clinical improvement in order to be considered for an additional category. The commenter stated that the statutory standard that no medical device be described by more than one category does not support the substantial clinical improvement criterion.

Response: The statute explicitly requires us to establish criteria that will be used for creation of additional categories. (Section 1833(t)(6)(B)(ii)(I) of the Act) This statutory requirement permits the criteria that we have established, including demonstration of substantial clinical improvement.

We are continuing to review the issue of technological change that is not associated with substantial clinical benefit to beneficiaries. We will continue to review applications for such devices on a case by case basis and work with applicants to understand exactly what technological changes were made to a device that would make the device eligible for transitional pass through payments. We solicit further examples of such devices so that, in the future, we may establish a more definite criterion for when such changes make a device eligible for transitional pass through payments.

Comment: Associations representing manufacturers stated that our assertion in the preamble of the November 2, 2001 interim final rule that says MedPAC's recommendation that pass-through payments for specific technologies be made only when a technology is new or substantially improved is a misinterpretation. The commenters asserted that MedPAC considers the concepts of improvements in devices themselves and substantial improvement to be separate, and that either of the two should be required for a criterion related to device improvement for pass-through eligibility.

Response: While we continue to believe that, in general, new technologies without a demonstrated substantial clinical benefit to beneficiaries should not receive transitional pass-through payments, we do review nominated devices for technological changes that are not associated with substantial clinical benefit to beneficiaries.

Comment: An association representing device manufacturers stated that our substantial clinical improvement criterion would significantly increase the time between FDA approval to market the device and recognition of the device for pass-through payment. The commenter claimed that this is counter to an objective of the pass-through payment mechanism as a means to promote rapid payment in the OPPS for new technology. This commenter, therefore, recommended replacing the criterion to demonstrate substantial clinical improvement with a requirement to demonstrate ''potential improvement.''

Similarly, another manufacturers' association asserted that clinical outcomes information should not be required for eligibility for a new pass-through category. This commenter suggested that our rules should request information that is appropriate and

relevant for the product and related procedures, which should include information other than published clinical trials.

Response: We are making every effort to minimize the time lag between FDA approval and establishment of a device category. We believe that we have succeeded in making timely decisions in this regard.

We will consider other information in addition to clinical outcomes that is available when clinical trial data are not yet available.

We do not know how one can demonstrate ''potential'' clinical improvement. ''Potential'' refers to the anticipated or possible capability, belief, or expectation for clinical improvement, without the evidentiary demonstration yet.

We do not believe potential improvement is an appropriate criterion. First, it would be difficult to prove; second, we would be in the position of potentially making extra payments for technologies that actually harmed beneficiaries. Thus using ''potential'' clinical improvement would assure that all new devices would meet such a criteria if the manufacturer asserted that the device in question offers a ''potential'' clinical improvement.''

Comment: Some commenters expressed concern with our rule that devices that are described by an existing category are not eligible for new categories. Some call for flexibility in applying this criterion, claiming that some of our category descriptors are too broad and confusing. One manufacturer was particularly concerned that newer technology pacemakers, internal cardioverter-defibrillators (ICDs), and pacemaker and ICD leads would be precluded from achieving new categories because they could be described by widely defined existing categories. The commenter stated that we should revise definitions of existing categories whenever necessary in order to accommodate the creation of new categories. Revising category descriptions to make them less broadly worded was one such example provided, including categories related to pacemakers, ICDs, and pacemaker and ICD leads.

Some commenters felt that new categories would need to be created in order to track cost of newer devices, even if they are described by existing categories. These commenters asserted that device costs eventually must be placed into APCs that appropriately reflect costs for future payment. Some commenters claimed that investigational devices that attained pass-through status have low procedural volumes and therefore they are underrepresented in the cost data.

Response: We believe that broadly defined categories are appropriate. Such categories are easier for coders to understand and allow devices to immediately receive transitional pass-through payments upon being marketed (instead of going through an application process). We have applied this criterion appropriately. There are devices that have been deemed eligible for a new category because the clinical applications are substantially different than devices of existing categories.

Some category descriptions have been modified when it has been brought to our attention that the descriptor is unclear. We first revised the descriptors of device categories in Program Memorandum A–01–73, effective July 1, 2001, in order to clarify the devices covered by categories. However, we do not intend to revise descriptors solely to allow the creation of new categories. If a device or class of devices is described by the categories we initially created, we will apply the criteria we implemented to determine whether an additional category is warranted. If we determine that an additional category is needed to adequately describe and pay for new devices, we will create a category. If in the course of that determination, we find that clarification of an existing or previously existing category is needed so that only one category describes the device, as required by statute, then we will modify the description of the existing or previously existing category or categories, in order to achieve that clarification.

We are maintaining our criteria to establish a new category of devices for pass-through payment.

Cost. We determine that the estimated cost to hospitals of the devices in a new category (including any candidate devices and the other devices that we believe will be included in the category) is ''not insignificant'' relative to the payment rate for the applicable procedures. The estimated cost of devices in a category is considered ''not insignificant'' if it meets the following criteria found in regulations at new § 419.66(d):

- The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices.
- The estimated average reasonable cost of devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent.
- The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.

Of these three cost criteria, the latter two remain unchanged from the existing thresholds for individual devices (however, as discussed below, their effective date was revised). The first criterion, however, represents a change in the percentage threshold.

In the April 7, 2000 final rule, we provided that a device's expected reasonable cost must exceed 25 percent of the applicable APC payment for the associated service as the criterion for determining when the cost of a specific device is ''not insignificant'' in relation to the APC payment (65 FR 18480). In the August 3, 2000 interim final rule, we lowered the threshold to 10 percent because we believed the 25 percent limit was too restrictive based on the brand specific approach at the time (65 FR 47673; § 419.43(e)(1)(iv)(C)). However, given our payment experience in 2001 using the 10 percent threshold, including our information on the estimated amount of pass-through payments in CY 2002, we determined a higher threshold was warranted. We believed that setting a higher cost threshold ensures that new categories are created only in those instances where they are most valuable to beneficiaries and hospitals, given the overall limits on pass-through payments. That is, pass-through payments will be targeted only to those devices where cost considerations might be most likely to interfere with patient access.

We found that once we lowered the threshold to 10 percent, a very small minority (less than 10 percent) of devices that met all other criteria for the pass-through payment was rejected on the basis of this criterion. Partly as a result, the list of devices qualified for pass-through payments increased to well over 1,000 devices by the end of 2000. Although the extensive number of qualified devices allowed hospitals to receive additional payment for many devices, we estimated that the overall pass-through payment amount for calendar year 2002 would exceed the 2.5 percent cap. Therefore, for that year, a substantial reduction in the amount of each pass-through payment, as required by section 1833(t)(6)(E)(iii) of the Act, was established. Thus, allowing a large number of marginally costly devices to qualify for the pass-through payment

would reduce the amount of additional payment a hospital would receive for any one device. We believe raising the threshold for this criterion benefits hospitals by focusing the pass-through payments on those devices that represent a substantial loss to the hospital. We believe this change also preserves beneficiary access to especially expensive devices.

In addition, once a category is established, devices included in the category are eligible for pass-through payments regardless of the cost of the devices. Therefore, we determined that it is reasonable to set a higher threshold than 10 percent to establish a new category. While the cost of most devices described by a category may equal or exceed the threshold we use in establishing a category, the cost of individual devices could easily fall below the threshold. Therefore, we believe that it is reasonable to use a higher threshold in establishing a category than in qualifying individual devices.

Concerning the latter two criteria for determining that the estimated cost of a category of devices is not insignificant, we intended to apply these criteria to devices for which a pass-through payment is first made on or after January 1, 2003, as we provided in the August 3, 2000 interim final rule (65 FR 47673). We stated that the delay would allow us sufficient time to gather and analyze data needed to determine the current portion of the APC payment associated with the devices.

Based on the outpatient claims data we have been using for analysis, we have been able, in many cases, to use these criteria as of the November 2, 2001 interim final rule. Although the 1996 data did not provide a level of information that allowed us to determine the portion of the APC payment that was related to the device (except in a very few cases such as pacemakers), the later data have generally provided this level of detail. Therefore we applied the second and third cost criteria for the purpose of determining eligibility of proposed new categories, as described in regulations at § 419.66(d)(2) and § 419.66(d)(3), as soon after the implementation of the November 2, 2001 interim final rule as we had data to do so rather than on January 1, 2003. Although in some instances the lack of specific data prevented the application of these criteria, we believed that should not delay our use of these criteria in those situations in which the data have been available.

In order to implement these second and third criteria for the purpose of creating new device categories, it is necessary to obtain the cost of the device-related portion of the APC payment amount. For evaluations of device category applications in 2002, we used the device-offset amounts published in our March 1, 2002 final rule (67 FR 9557 through 9558), which are used to calculate the subtractions to device pass-through payments. For 2003, we will use the device-offset amounts found in Table 11 in this rule as the device-related portion of the APC payment needed for cost criteria 2 and 3. The device-offset amounts represent the device costs that have been folded into the respective APC payment rates. In those cases where an application is received in which the service-related HCPCS codes for the device is mapped to no APC that has a device offset amount, we apply only the first cost criterion.

Comment: Some commenters wrote that while we need to limit pass-through payments for new categories to those devices that are clearly underpaid relative to the APC rates, our ''not insignificant'' cost tests set the bar too high. Some held that this is particularly the case for APCs with high relative weights and consequent payments, in which our 25 percent minimum percentage of the APC as well as the device offset represent a significant cost to the hospital in absolute terms. Commenters proposed alternate percentage thresholds with specific dollar caps (for example, 20 percent of the APC payment or $1,000, whichever is less).

Response: In the cases of APCs with high relative weights and payment rates, such payments already encompass much of the costs of devices. The thresholds in dollar terms in those cases should be set higher to test for cost significance. We have heard from many commenters to our August 9, 2002 proposed rule that many device costs consist of a large percentage of the APC cost. The ratio method (for example, 25 percent) therefore equitably accounts for APC payment differences for devices.

We do not see any compelling reason to adopt the proposed alternate percentages of the APC amount as the threshold of using as an alternative to our current cost significance threshold of 25 percent for device portions related to any respective APC. Moreover, the initial pass-through categories were based on devices that achieved pass-through status with a lower 10 percent threshold.

Comment: Another commenter claimed that the statutory language demonstrates the congressional intent that only the cost of the devices in a category be compared to the applicable APC payment. Therefore, only the first of our three prongs to test cost significance of a new device should be used. This commenter claimed that section 1833(t)(6) of the Act states that we shall provide pass-through payments only for categories of devices when ''the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount * * * .'' The commenter further advocated that our criteria be amended to reflect that a proposed category of devices be required to meet any one of the three prongs, to give some weight to the potential benefits of the second and third prongs.

Response: The statute requires that the average cost of a new device category is not insignificant in relation to the OPD fee schedule amount payable for the service or group of services involved. The statute further requires the Secretary to establish criteria for creating additional categories, including criteria for cost significance. Beyond those requirements, the statute allows the Secretary the discretion to determine how to apply the cost significant criterion.

In developing the specific criteria for meeting the statutory cost significance requirement, we established thresholds which we believe ensure that new categories are created where they are most valuable to beneficiaries and hospitals, given the overall limits on pass-through payments. Our goal is to target pass-through payments at those devices where cost considerations might be most likely to interfere with patient access.

To properly target the pass-through payments at devices that could represent a substantial loss to the hospital, it is important to both assess the incremental cost of performing the procedure using the new device as well as to compare the cost of the new device against the costs of existing devices already packaged into the APC payment for the procedure.

The first prong of our three prong criterion tests only the relationship of the new device to the cost of the entire procedure whereas the second and third prongs test for the relationship to device costs already incorporated into the payment rate for the procedure.

Comment: A hospital organization supported our two major criteria for establishing an additional device category for pass-through payment, that is, that a category of devices must demonstrate substantial clinical improvement and have costs that are ''not insignificant'' in relation to the APC payment. In particular, the

organization supported our decision to raise the threshold that device costs for a new category must exceed 25 percent of the related APC payment, as well as our re-institution of the two additional prongs of the not-insignificant cost test. However, the commenter noted that we had previously delayed the implementation of these latter two prongs of the ''not insignificant'' cost criterion until January 1, 2003, so that we could ensure reliable and accurate data to make the cost estimates. The organization would support the reinstitution of these cost prongs that establish that costs are not insignificant only when CMS has sufficiently accurate and reliable data to make such estimates. The commenter also believes that the data and methodology should be made available to the public for review.

This organization also felt that the (then) current number of initial categories is appropriate. It urged us to make application information regarding any proposed new categories public for comment before final creation of a new category.

Response: Based on the outpatient claims data we have been using for analysis, we have been able, in many cases, to use the second and third cost criteria since the November 2, 2001 interim final rule became effective. Although the 1996 data did not provide a level of information that allowed us to determine the portion of the APC payment that was related to the device (except in a very few cases such as pacemakers), the later data we have used has generally provided this level of detail. Therefore, we applied the second and third cost criteria. As noted earlier, for 2002, we have used the device offsets we calculated for subtracting the cost of existing devices in APCs as the portion of the APC payment related to the device. We feel the offsets have been appropriate as this portion of the APC payment, and we will use them for 2003 as well. We therefore feel this commenter's concerns have been addressed.

We will continue to use the three prongs of the not insignificant cost test as published in the November 2, 2001 interim final rule.

1. Application Process for Creation of a New Device Category

Device manufacturers, hospitals, or other interested parties may apply for a new device category for transitional pass-through payments. Details regarding the informational requirements, deadlines for quarterly review, and other aspects of the application process are available on our Web site, *http://cms.hhs.gov.*

We will accept applications at any time. However, we will establish new categories only at the beginning of a calendar quarter, in deference to our computer systems needs and those of our contractors and hospitals. We must receive applications in sufficient time before the beginning of the calendar quarter in which a category would be established to allow for decision-making and programming. For now, we will require that applications be received at least 4 months before the beginning of the quarter. Moreover, we have found, that, due to the complexity of the information and review process for additional categories, we cannot always complete our review within that time frame. Review of applications involving devices with new technologies often involves requesting additional information from the applicants, as well as consultation with experts in certain clinical specialties (usually here at CMS) or with other clinical personnel at CMS with expertise in Medicare coverage issues, as needed (for example, the hearing aid issue).

We may change the details of this application process in the future to reflect experience in evaluating applications and programmatic needs. If we revise these instructions, we will submit the revisions to the Office of Management and Budget under the Paperwork Reduction Act. We will also post the revisions on our Web site.

Comment: One commenter recommended that we post draft new categories and any draft changes to existing categories to our Web site for public review and comment before final publication, as a collaborative, informal process to be accomplished within the 4-month quarterly application evaluation and update time frame.

Response: Such process could not be accomplished within the 4-month time frame. We note that the greater part of the four month period is consumed in systems changes, not review of the application, so little time is available for further information. Thus, further consultation would result in longer timeframes for action. We have listened and met with many parties concerning recommendations for additional categories and heard their concerns related to our existing and new categories and will continue to do so. However, we believe that the review, evaluation, and decision process and publication process for new category applications to meet the closest feasible quarterly updates is already compact. However, we will continue to consider informal comments or feedback from hospitals, manufacturers, and other parties regarding our decisions.

Comment: An association of manufacturers of brachytherapy sources and other brachytherapy devices recommended that we establish several specific new categories.

Response: We have established a uniform method for evaluating applications for new categories, based on the application information published on our Web site. We evaluate the necessity of new categories based on the specific information we receive, such as clinical differences between items nominated for the new categories and the existing or previously existing categories. We therefore are not able to react to the specific categories recommended through public comments by this commenter without complete applications on the subject brachytherapy sources.

We are making no change to our application process at this time.

2. Announcing a New Device Category

When we determine a new category is warranted, we issue a Program Memorandum specifying a new Healthcare Common Procedure Coding System (HCPCS, formerly known as HCFA Common Procedure Coding System) code and short and long descriptors for the category. We may also include additional clarifying or definitional information to help distinguish the new category from other existing or previously existing categories. It may be necessary to redefine, or make other changes to, existing or previously existing categories to accommodate a new category and ensure that no medical device is described by more than one category, though we attempt to keep these changes to a minimum. We will post these Program Memoranda on our Web site on a quarterly basis. We may find it necessary occasionally to correct or amend the list of (and clarifying information associated with) pass-through device categories. We do not expect this step will be needed often, but if it is necessary, we will issue any changes in a Program Memorandum.

VI. Wage-Index Changes for Calendar Year 2003

Section 1833(t)(2)(D) of the Act requires that we determine a wage adjustment factor to adjust for geographic wage differences, in a budget-neutral manner, the portion of the OPPS payment rate and copayment amount that is attributable to labor and labor-related costs.

We used the proposed Federal fiscal year (FY) 2003 hospital inpatient PPS

wage index to make wage adjustments in determining the proposed payment rates set forth in the proposed rule. We also proposed to use the final FY 2003 hospital inpatient wage index to calculate the final CY 2003 payment rates and coinsurance amounts for OPPS. We used the final Federal FY 2003 hospital inpatient PPS wage index to make wage adjustments in determining the final payment rates set forth in this final rule with comment. The final FY 2003 hospital inpatient wage index published in the August 1, 2002 **Federal Register** (67 FR 39858) is reprinted in this final rule with comment as Addendum H—Wage Index for Urban Areas; Addendum I—Wage Index for Rural Areas; and Addendum J— Wage Index for Hospitals That Are Reclassified. We use the final FY 2003 hospital inpatient wage index to calculate the payment rates and coinsurance amounts published in this final rule with comment to implement the OPPS for CY 2003. We note, however, that from time to time, there are mid-year corrections to these wage indices and that our contractors will adopt and implement the mid-year charges for OPPS in the same manner that they made mid-year changes for inpatient hospital prospective payment.

Comment: A commenter asked for an explanation of the rationale behind applying the area wage index to the device component of an APC. Also, another commenter urged us to clarify that APCs for drugs and biologicals would not be subject to geographic wage adjustment since the APC payment rates primarily reflect drug acquisition costs, not labor costs.

Response: Our rationale for applying the area wage index to the device component of an APC is that once a device cost is packaged into a procedure APC, we do not differentiate between which costs in the APC should or should not have the area wage index applied. We believe that it would be complicated and prone to error to segment out a device component of the APC and determine the appropriate portion of the APC payment amount that consists of device cost only. To address the second issue, we would like to clarify that we do not apply the area wage index to payment rates for drugs and biologicals that are assigned to the status indicator G or K.

VII. Copayment for Calendar Year 2003

Section 1833(t)(8)(C)(ii) of the Act accelerates the reduction of beneficiary copayment amounts, providing that, for services furnished on or after April 1, 2001, and before January 1, 2002, the national unadjusted coinsurance for an APC cannot exceed 57 percent of the APC payment rate. The statute provides that the national unadjusted coinsurance for an APC cannot exceed 55 percent in 2002 and 2003. The statute provides for further reductions in future years so that the national unadjusted coinsurance for an APC cannot exceed 55 percent of the APC payment rate in 2002 and 2003, 50 percent in 2004, 45 percent in 2005, and 40 percent in 2006 and thereafter.

For 2003, we determined copayment amounts for new and revised APCs using the same methodology that we implemented for 2002 (see the November 30, 2001 final at 66 FR 59888). See Addendum B for national unadjusted copayments for 2003. Our regulations at § 419.41 conform to this provision of the Act.

VIII. Conversion Factor Update for Calendar Year 2003

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis.

Section 1833(t)(3)(C)(iv) of the Act provides that for 2003, the update is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act.

The most recent forecast of the hospital market basket increase for FY 2003 is 3.5 percent. To set the proposed OPPS conversion factor for 2003, we increased the 2002 conversion factor of $50.904 (the figure from the March 1, 2002 final rule (67 FR 9556)) by 3.5 percent.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for 2003 to ensure that the revisions we made to update the wage index are made on a budget-neutral basis. We calculated the proposed budget-neutrality factor of .98778 for wage-index changes by comparing total payments from our simulation model using the proposed FY 2003 hospital inpatient PPS wage-index values to those payments using the current (FY 2002) wage-index values.

The increase factor of 3.5 percent for 2003 and the required wage-index budget-neutrality adjustment of .98715 resulted in a proposed conversion factor for 2003 of 52.009.

In determining the proposed conversion factor of 52.009, we projected 2.5 percent pass-through payments based on our preliminary estimates of pass-through payments for CY 2003. As described in the section IV discussion of the pro-rata provisions, our final estimate of pass-through payments in CY 2003 is 2.3 percent of the total program payments for covered OPD services. Therefore, we have increased the final conversion factor to reflect the projected change in pass-through spending from 2.5 percent to 2.3 percent. After applying this adjustment, the 3.5 percent update factor and the final budget-neutrality adjustment of .98778 to account for changes due to the final FY 2003 hospital inpatient wage-index values, we establish the final conversion factor for 2003 at $52.151 (or 52.152).

We received several comments concerning the conversion factor update for 2003, which are summarized below along with our responses.

Comment: Several commenters contended that CMS imposed excessive pro-rata reductions in 2002, which exacerbated the inadequacy of Medicare payments and urged CMS to use its statutory authority under section 1833(t)(3)(C)(iii) to adjust the 2003 conversion factor for the unexpectedly low pass-through payments made in 2002.

Response: The commenters' estimates are based on 2001 claims. We do not know yet whether there will be excessive pro-rata reductions in 2002 because at the time of this rule, we do not have more than first-quarter 2002 claims data available. Therefore, it would not be appropriate to make such an adjustment. Furthermore, we do not believe that the statute permits us to make retroactive adjustments.

Comment: One commenter stated that the statute requires the conversion factor to be updated by the full increase in the hospital inpatient market basket of 3.5 percent, but the application of a budget-neutrality factor of .987156 results in an update factor of only 2.17 percent. Another commenter indicated the belief that the amount of reduction from the 3.5 percent market basket update is excessive and beyond what is required to achieve statutory goals. The commenter recommended that the 2003 conversion factor be increased.

Response: Statute requires us to ensure that a conversion factor for covered OPD services in subsequent years is an amount equal to the conversion factor applicable to the previous year before any increases due to the market-basket increase. In order to ensure that we maintain budget neutrality (except for the market-basket increase), we must make an adjustment to account for changes in the wage index. To do so, we calculate the total payments for 2002, using the 2002 wage index and weights, and compare that result to total payments calculated by applying the new 2003 wage index to

the 2002 APC weights. For 2003, that comparison resulted in the .969 adjustment.

IX. Outlier Policy for Calendar Year 2003

For OPPS services furnished between August 1, 2000, and April 1, 2002, we calculated outlier payments in the aggregate for all OPPS services that appear on a bill in accordance with section 1833(t)(5)(D) of the Act. In the November 30, 2001 final rule (66 FR 59856, 59888), we specified that beginning with 2002, we will calculate outlier payments based on each individual OPPS service. We revised the aggregate method that we had used to calculate outlier payments and began to determine outliers on a service-by-service basis.

As explained in the April 7, 2000 final rule (65 FR 18498), we set a target for outlier payments at 2.0 percent of total payments. For purposes of simulating payments to calculate outlier thresholds, we proposed to set the target for outlier payments at 2.0 percent. The target was 2.0 percent for CY 2001 and 1.5 percent for 2002. For 2002, the outlier threshold is met when costs of furnishing a service or procedure exceed 3.5 times the APC payment amount, and the current outlier payment percentage is 50 percent of the amount of costs in excess of the threshold. Based on our simulations for 2003, we proposed to set the threshold for 2003 at 2.75 times the APC payment amounts, and the proposed 2003 payment percentage applicable to costs over the threshold at 50 percent.

In this final rule we are setting the target amount for outlier payments at 2 percent of total payments. Based on revised simulations performed for the final rule, in order to pay outlier payments at the target amount, we are adopting the proposed outlier threshold of 2.75 but decreasing the outlier payment percentage to 45 percent. Simulations using the final APC rates and projecting outlier payments for 2003 using a different set of claims than we used for the proposed rule (claims for the period April 1, 2001 through March 31, 2002 instead of claims for calendar year 2001) resulted in outlier payments that were in excess of the 2 percent outlier payment target. In order to meet, but not exceed, the target we found it necessary to either increase the proposed outlier threshold of 2.75 or reduce the proposed outlier payment percentage of 50 percent. Because we wanted to make it easier for more for high cost services to qualify for outlier payments, we chose to adopt the proposed outlier threshold but reduce the outlier payment percentage to 45 percent. For 2003, the outlier threshold will be met when costs of furnishing a service or procedure exceed 2.75 times the APC payment amount, and the outlier payment percent will be 45 percent of the amount of costs in excess of the threshold.

We received a number of comments concerning our proposed threshold and percentages for outlier payments, which are summarized below along with our responses. We also received comments concerning the changes that we proposed and finalized in 2002 with respect to the calculation of outliers on a service-by-service basis. Because we have not proposed any changes to the current policy, we do not summarize those comments in this preamble.

Comment: A number of commenters commended CMS on lowering the outlier threshold, but they urged CMS to reduce the threshold even further. The commenters also said that the outlier payment percentage of 50 percent of costs in excess of the outlier threshold was not sufficient to offset the losses hospitals incur in high-cost cases. Some of these commenters urged CMS to adopt the same marginal payment rate of 80 percent that is used for calculating outliers under the inpatient PPS.

Response: Under the OPPS, CMS must address two needs: the need to balance payment for high-cost cases with the need to ensure that appropriate payments are made for basic services for the average patient population. By setting our outlier target of 2 percent, we believe that we have struck the right balance to accomplish these goals.

Comment: According to one commenter, new technologies and drugs are expanding too rapidly for CMS to appropriately account for the costs in the APCs, which is a particular concern at larger hospitals that provide a wide scope of services and access to new technologies and drugs. The commenter said that outliers can help defray the costs of new technologies until adequately reflected in the APC payments and urged CMS to consider expanding the outlier target from 2 percent to 2.5 percent. Another commenter contended that the transition of expiring pass-through items into APCs will result in dramatic payment reductions and urged CMS to reduce the outlier threshold to 2.5 times the APC payment amount for 2003 and increase the outlier target as close as possible to the statutory maximum of 2.5 percent of total payments.

Response: As described elsewhere in this final rule, the recalibration of weights based on newer data and the additional steps that we have taken to limit the payment reductions should decrease the need for outliers. Also, the pass-through provisions for new drugs and devices and our payment mechanism for new technology procedures provide hospitals with an additional mechanism to defray costs for emerging technologies.

Comment: A number of commenters said that CMS does not provide sufficient data to support how outlier payments and thresholds are determined and to ensure that outlier payments are being made in the range of 2 percent to 2.5 percent. Additional outlier data that the commenters requested include information such as the actual outlays as compared to forecasted outlays 2001, estimated outlays for 2002, the historical outlier percentage of total OPPS payments, and information on the types of cases that are qualifying for outlier payments. The commenters wanted CMS to provide supporting information in the final rule, just as it does for the inpatient PPS.

Response: We agree with the commenters that we should provide this data. However, due to the time constraints in producing this final rule, we are unable to add this information to this preamble. Nonetheless, we will post this information to our Web site shortly after publication of the rule. We will notify the public through the CMS listserv when the information is available. To subscribe to this listserv, please go to the following Web site: *www.cms.hhs.gov/medlearn/listserv.* Follow the directions for subscribing to the OPPS listserv to get the most up-to-date information on OPPS directly from CMS.

Comment: One commenter expressed concern that CMS has made significant changes to the outlier target and eligibility thresholds in 2002 and 2003, in opposite directions, without sufficiently supporting the changes with experiential data. The commenter maintained that, in aggregate, outlier payments as a percentage of total payments should remain relatively predictable and, therefore, questions whether the experience in 2001 and 2002 would support the significant swings in funding and thresholds.

Response: It is too early for us to tell what the 2002 experience has been like in order to compare it to the 2001 experience. Nevertheless, as indicated in the previous response, we will also notify the public and share the 2001 data on our Web site.

Comment: One commenter urged CMS to provide clarification regarding the rationale to decrease the cost threshold that permits more items to qualify for outlier payments, rather than

to increase the payment percentage from its current level of 50 percent, which would provide more payments for high-cost cases.

Response: We apply an iterative process in which we try different combinations of thresholds and payment percentages until an appropriate combination results in outlier payments under our simulation that is equal to the target percentage of total OPPS payments. While some fluctuation is expected each year due to the use of newer and better data and policy changes, we attempt both to strike a balance and to prevent (to the extent possible) large changes in the outlier payments to hospitals. A significant increase in the threshold would limit the number of services and hospitals that qualify for outlier services.

Comment: One commenter expressed concern that without correcting for the significant reductions proposed for a number of high-cost APCs, those services may unnecessarily qualify for outlier payments because the costs that go into the outlier calculation are calculated using a hospital's overall cost-to-charge ratio (CCR), which may be higher than the departmental CCRs used to determine costs for payment-rate calculations. The commenter contends that, if this occurs, it will result in outlier payments that are higher than anticipated, which could unduly raise thresholds in the future and affect the integrity of the outlier policy.

Response: As described elsewhere in this rule, we believe that the adjustments we have made to many APC rates for this final rule will address the commenter's concerns about services unnecessarily qualifying for outlier payments.

X. Other Policy Decisions and Changes

A. Hospital Coding for Evaluation and Management (E/M) Services

Background

Currently, facilities code clinic and emergency department visits using the same current procedural terminology (CPT) codes as physicians. For both clinic and emergency department visits, there are five levels of care. While there is only one set of codes for emergency visits, clinic visits are differentiated by new patient, established patient, and consultation visits. CPT codes 99201 through 99205 are used for new patients, CPT codes 99211 through 99215 are used for established patients, and CPT codes 99281 through 99285 for emergency patients.

Physicians determine the proper code for reporting their services by referring to CPT descriptors and our documentation guidelines. The descriptors and guidelines are helpful to physicians because they reference taking a history, performing an examination, and making medical decisions. The lower levels of service (for example, CPT codes 99201, 99211, and 99281) are used for shorter visits and for patients with uncomplicated problems, and the higher levels of service (for example, CPT codes 99205, 99215, and 99285) are used for longer visits and patients with complex problems.

These codes were defined to reflect the activities of physicians. It is generally agreed, however, that they do not describe well the range and mix of services provided by facilities to clinic and emergency patients (for example, ongoing nursing care, preparation for diagnostic tests, and patient education).

Before the implementation of the OPPS, facilities were paid on the basis of charges reduced to costs. In that system, because use of a correct HCPCS code did not influence payment, there was little incentive to correctly report the level of service. In fact, many facilities reported all clinic and emergency visits with the lowest level of service (for example, CPT codes 99211, 99201, and 99281) simply to minimize administrative burden (for example, charge-masters might include only one level of service).

This situation changed with the implementation of the OPPS. The OPPS requires correct reporting of services using HCPCS codes as a prerequisite to payment. For emergency and clinic visits, the OPPS distinguishes three levels of service for payment purposes. These are referred to as ''low-level,'' ''mid-level,'' and ''high-level'' emergency or clinic visits. Payment rates for low-level visits are less than for mid-level visits, which are less than rates for high-level visits.

In the April 7, 2000 final rule (65 FR 18434), we stated that to pay hospitals properly, it was important that emergency and clinic visits be coded properly. To facilitate proper coding, we required each hospital to create an internal set of guidelines to determine what level of visit to report for each patient. We stated in the rule, that if hospitals set up these guidelines and follow them, they would be in compliance with OPPS coding requirements for the visits. Furthermore, we announced that we would be reviewing this issue and planned to set national guidelines for coding clinic and emergency visits in the future. In the August 24, 2001 proposed rule (66 FR 44672), we asked for public comments regarding national guidelines for hospital coding of emergency and clinic visits. We also announced that we would compile these comments and present them to our APC Panel at the January 2002 meeting. We also announced that we planned to propose uniform national facility coding guidelines in the proposed rule for the 2003 OPPS.

During its January 2002 meeting, the APC Panel reviewed written comments, heard oral testimony, discussed the issue, and made recommendations concerning establishment of facility coding guidelines for emergency and clinic visits. Among those who submitted oral and written comments to us and to the Panel were national hospital organizations, national physician organizations, hospital systems, individual hospitals, coding organizations, and consultants.

APC Panel Recommendations

The APC Panel reviewed the comments that we received, reviewed background material we prepared, and heard oral testimony. Most commenters recommended that we adopt the ACEP guidelines. However, one organization representing cancer centers stated that the most appropriate proxy for facility resource consumption in cancer care is staff time and asked that we consider basing our guidelines on staff time. Commenters agreed that we needed to address this problem in the proposed rule for CY 2003. They also agreed that to address potential HIPAA compliance issues, we should develop new HCPCS codes for facility visits; and that we should maintain five levels of service for emergency and clinic visits until data are available to show that only three levels of service are required to ensure accurate payments. Commenters also agreed that, for the same level of service, clinic resource consumption should be similar for new, established, and consultation patients. Therefore, we need only create a single set of five codes for clinic visits.

After a thorough discussion, the APC technical panel made the following recommendations:

1. Propose and make final facility coding guidelines for E/M services for calendar year 2003.

2. Create a series of G codes with appropriate descriptors for facility E/M services.

3. Maintain a single set of codes, with five levels of service, for emergency department visits.

4. Develop a single set of codes, with five levels of service, for clinic visits.

The Panel specifically recommended that we not differentiate among visit types (for example, new, established, and consultation visits) for the purposes of facility coding of clinic visits.

5. Adopt the ACEP facility coding guidelines as the national guidelines for facility coding of emergency department visits.

6. Develop guidelines for clinic visits that are modeled on the ACEP guidelines but are appropriate for clinic visits.

7. Implement these guidelines as interim and continue to work with appropriate organizations and stakeholders to develop final guidelines.

Proposed Rule

We reviewed the written comments, the oral testimony before the APC Panel, and the Panel's recommendations; we agreed that facility-coding guidelines should be implemented as soon as possible. We were particularly concerned that facilities be able to comply with HIPAA requirements. We announced that we have worked, and will continue to work, on this issue with hospitals, organizations representing hospitals, physicians, and organizations representing physicians. We noted that the AMA CPT Editorial Panel is not currently considering the issue of facility coding guidelines for clinic visits and that the earliest any CPT guidelines could be implemented would be in January 2004. Additionally, consistent with the intent of the outpatient prospective payment system, we wanted to ensure that reporting of hospital emergency and clinic visits is resource based.

After careful review and consideration of written comments, oral testimony and the APC Panel's recommendations, we proposed the following (for implementation no earlier than January 2004):

1. To develop five G codes to describe emergency department services: GXXX1—Level 1 Facility Emergency Services, GXXX2—Level 2 Facility Emergency Services, GXXX3—Level 3 Facility Emergency Services, GXXX4—Level 4 Facility Emergency Services, and GXXX5—Level 5 Facility Emergency Services.

2. To develop five G codes to describe clinic visits: GXXX6—Level 1 Facility Clinic Services, GXXX7—Level 2 Facility Clinic Services, GXXX8—Level 3 Facility Clinic Services, GXXX9—Level 4 Facility Clinic Services, and GXXX10—Level 5 Facility Clinic Services.

3. To replace CPT Visit Codes with the 10 new G codes for OPPS payment purposes.

4. To establish separate documentation guidelines for emergency visits and clinic visits.

With regard to the documentation guidelines, our primary concerns were to make appropriate payment for medically necessary care, to minimize the information collection and reporting burden on facilities, and to minimize any incentive to provide unnecessary or low quality care. We realized that many facilities use complaint or diagnosis driven care protocols and that current documentation standards do not include documentation of staff time or the complexity of diagnostic and therapeutic services provided. Therefore, in the interest of facilitating the delivery of medically necessary care in a clinically appropriate way, we believed that the potential drawbacks of each of the recommended sets of guidelines outweighed the potential benefits of creating uniformity and reproducibility. For example, any documentation system requiring counting or quantification of resource use has the potential to be burdensome, require clinically unnecessary documentation, and be susceptible to upcoding and gaming. Documentation systems using coding grids or a series of clinical examples for each level of service are subject to interpretation, may induce variability, may be overly complex and burdensome, and may result in disagreements with medical reviewers. We were also concerned that all the proposed guidelines allow counting of separately paid services (for example, intravenous infusion, x-ray, EKG, lab tests, and so forth) as ''interventions'' or ''staff time'' in determining a level of service. We believe that, within the constraints of clinical care and management protocols, the level of service for emergency and clinic visits should be determined by resource consumption that is not otherwise separately payable.

To address these concerns, in addition to reviewing written comments, oral comments, and the APC Panel recommendations, we also reviewed, for the proposed rule, the current distribution of paid emergency and clinic visit codes in the OPPS. With regard to emergency visits, we observed that well over 50 percent of the visits were considered ''multiple procedure claims'' because the claim includes services such as diagnostic tests (for example, EKGs and x-rays) or therapeutic interventions (for example, intravenous infusions). The distribution of all emergency services was in a bell-shaped curve with a slight left shift because there were more claims for CPT codes 99281 and 99282 than for CPT codes 99284 and 99285. This pattern of coding is significantly different from physician billing for emergency services, which is skewed and peaks at CPT code 99284. We also noted that the median costs for successive levels of emergency visits show an expected increase across APCs.

With regard to clinic visits, we observed that more than 50 percent of the services were considered ''single claims'' meaning that they were billed without any other significant procedures such as diagnostic tests or therapeutic interventions. We also noted that the distribution of clinic visits is skewed with the majority being low-level clinic visits. This distribution was consistent with pre-OPPS billing patterns where many facilities billed all clinic visits as low level visits. However, the median costs for different levels of clinic services, while similar within an APC, did not show the expected increase across the clinic visit APCs.

Based on our review, on the current distribution of coding for emergency and clinic visits, and on our understanding that hospitals set charges for services based on the resources used to provide those services, we believed that an incremental approach to developing and implementing documentation guidelines for emergency and clinic visits was appropriate. For example, as hospitals became more familiar with the OPPS and with the need to differentiate emergency and clinic visits based on resource consumption, we would continue to review the advantages and disadvantages of detailed, uniform documentation guidelines. We planned to begin the development of uniform guidelines over the next year. If we were ready, we would propose the guidelines for comments in our **Federal Register** document for the CY 2004 update. For CY 2003, we proposed the following new codes:

Emergency Visits

Because, our data indicated that, in general, hospitals under the OPPS were reporting emergency visits appropriately, we believed that insofar as hospitals have existing guidelines for determining the level of emergency service, those guidelines reflected facility resource consumption. Therefore, we proposed that GXXX1—Level 1 Facility Emergency Services be reported when facilities deliver, and document, basic emergency department services. These services included registration, triage, initial nursing assessment, minimal monitoring in the emergency department (for example,

one additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. We expected that these services would be delivered to patients who present with minor problems of low acuity.

With regard to GXXX2 through GXXX5, we proposed to require that facilities develop internal documentation guidelines based on hospital resource consumption (for example, staff time). These guidelines would be appropriate for the type of services provided in the hospital and also clearly differentiate the relative resource consumption for each level of service so that a medical reviewer could easily infer the type, complexity, and medical necessity of the services provided and validate the level of service reported. Because of the great variability in available facility resources, staff, and clinical protocols among facilities, we did not believe that it is advisable to require a single set of guidelines for all facilities. Instead, we believed it is appropriate for each facility to develop its own documentation guidelines that took into account the facility's clinical protocols, available facility resources, and staff types. As stated above, we did not propose any specific requirements with regard to the basis of these guidelines. However, the guidelines were to be tied to actual resource consumption in the emergency department such as number and type of staff interventions, staff time, clinical examples, or patient acuity. We also proposed to require that facilities have documentation guidelines available for review upon request. The guidelines had to emphasize relative resource consumption and not, to the extent possible, set minimal requirements as a basis for determining the level of service (for example, require 30 minutes of staff time or five staff interventions to bill a level three emergency visit).

We proposed that these requirements, if made final, would be interim. We proposed to work with interested parties to revise these requirements and to propose any revision to these requirements in a future proposed rule.

Clinic Visits

We believed that the current distribution of codes for clinic visits were due to a facility's continued use of pre-OPPS coding policies for clinic visits. We believed that over time facilities would become as experienced differentiating levels of clinic visits as they were at differentiating levels of emergency visits. Therefore, we proposed a set of guidelines for clinic visits that paralleled the requirements for emergency visits. We proposed that GXXX6—Level 1 Facility Clinic Services, be reported when facilities deliver, and document, basic clinic services. These services included registration, triage, initial nursing assessment, minimal monitoring in the clinic (for example, one additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. Our proposal for GXXX7 through GXXX10 was the same as for GXXX2 through GXXX5 except that the facility-specific guidelines were tied to actual resource consumption in the clinic such as number and type of staff intervention, staff time, clinical examples, or patient acuity. The guidelines had to differentiate the relative resource consumption in the clinic for each level of service sufficiently so that a medical reviewer could easily infer the type, complexity, and medical necessity of the services provided to validate the level of service provided.

We proposed that, if made final, these requirements would be interim. Any changes would be proposed in a future proposed rule.

We proposed to make final, in the 2003 OPPS final rule, changes in coding for clinic and emergency department visits and requirements related to the development of documentation guidelines for the new codes. However, we proposed to implement the new codes and documentation guidelines no earlier than January 1, 2004. This would have given hospitals time to develop documentation guidelines for the new codes and prepare their internal billing systems to accommodate the changes. We proposed to continue to work with hospitals throughout CY 2003 as they developed the documentation guidelines. In the proposed rule, we solicited comments on this proposal overall as well as the specific components of the proposal.

Comment: Many commenters recommended that CMS should keep the current E/M coding system until national coding guidelines with standard definitions can be established. Commenters also recommended that CMS convene a panel of experts to develop standard code definitions and guidelines that are simple to understand and implement and that allow for compliance with HIPAA requirements. Commenters generally recommended that code definitions and guidelines be established and implemented in 2003.

Response: We agree with many of the commenters concerns. While we agree that standard code definitions and guidelines should be implemented as soon as possible, we want to ensure that those definitions and guidelines are developed using an open process involving a variety of experts (for example, clinicians, coders, and compliance officers) in the field. Furthermore, the process should include adequate time for the education of clinicians and coders and for hospitals to make the necessary changes in their systems to accommodate the codes and guidelines.

In view of the comments received we believe that the most appropriate forum for development of code definitions and guidelines is an independent expert panel that makes recommendations to CMS in time for CMS to propose specific code definitions in the next year's proposed rule. Organizations such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA) have such expertise and are particularly well equipped to provide the ongoing education of providers. We believe it is critically important to the development, acceptance, and implementation of code definitions and guidelines for the organizations that develop the guidelines to also maintain them, update them, and provide ongoing education to providers concerning them. We would be happy to work with such an expert panel as code definitions and guidelines are developed.

We encourage any independent expert panel sending recommendations to CMS concerning guidelines to carefully review the principles and requirements for codes and guidelines that we announced in the proposed rule. We still believe that any set of national guidelines must adhere to those principles and requirements (for example, guidelines must be resource-based). Moreover, we encourage any such panel to address our concerns about existing guidelines (for example, potential for upcoding) in its recommendations to CMS. For example, our Advisory Panel on APC Groups recommended that CMS adopt the facility coding guidelines developed by the American College of Emergency Physicians (ACEP). While we understand that those guidelines have widespread support in the hospital community and that an independent panel may review them while developing guidelines, we would encourage such a panel to review the

ACEP guidelines in light of the principles, requirements, and concerns we enunciated in the proposed rule.

CMS hopes to receive recommendations on code definitions in time to include them in the notice of proposed rulemaking for 2004. We agree with the commenters who were concerned about implementing code definitions without national guidelines, and we will not propose or finalize code definitions until national guidelines for them have been developed.

Comment: Several commenters believed that use of G codes to describe facility visits would cause problems with payment by non-Medicare payers for these services. They believed this problem would worsen if the G codes were not accompanied by guidelines.

Response: G codes are national codes and must be recognized by other payers, though other payers do not need to use these codes for payment. We are unsure if the commenters' assertions are true. However, as stated in the previous response, we do not plan to finalize new codes for these services until guidelines for their use have been developed. Moreover, we will work with CPT, as appropriate, to develop CPT codes for these services once we have finalized and implemented them.

Comment: One commenter asked that CMS provide protection for hospitals against fraud and abuse allegations stemming from the current ambiguous guidelines.

Response: We are unsure if the commenter is referring to the CPT guidelines as being ambiguous for facilities or if the concern is over allowing facilities to develop and implement facility-specific guidelines until national codes and guidelines are implemented. In any case, we believe that written facility guidelines-developed in accordance with the principles (which we enunciated in the proposed rule and reaffirmed in this final rule) and which are widely disseminated in the facility, accompanied by appropriate education of clinicians and coders, and made available to reviewers-should address the concerns of the commenters.

Comment: Several commenters voiced concerns about what activities should be described in possible guidelines (*e.g.*, use of time as a criterion for selecting a level of service), the burden on facilities of having to adapt to a new set of codes for visits, and any requirements for facilities to develop their own guidelines. One commenter listed several principles for the development of facility codes and descriptors (that is, codes and guidelines should: focus on resource use, be supported by medical record documentation, support code assignment by the chargemaster, and provide a means for benchmarking medical-visit data across the industry).

Response: We believe that having an independent panel develop guidelines and make recommendations to CMS will address the concerns of these commenters. With regard to requiring facilities to develop internal guidelines for visit services, we believe that development of internal guidelines is critical for ensuring appropriate medical review and for enabling facilities to prove that billing for services were actually rendered.

Comment: One commenter asked CMS to clarify the terms ''nursing assessment'' and ''nursing discharge'' when assigning a level of service to a visit.

Response: Because we expect to receive recommendations from an independent panel regarding coding guidelines, we will not finalize the proposal describing what constitutes a level one emergency or clinic visit. Instead, we will continue to allow hospitals to develop their own internal guidelines for such visits until we finalize codes and guidelines.

Comment: One commenter asked that we create five payment rates for emergency and clinic visits, one for each level of service—instead of the three payment rates that we currently use.

Response: We review the relative weights of each APC on a yearly basis, and we would consider such a change if our claims data indicated such a change is appropriate.

Comment: One commenter asked that we craft a surgical global package for facilities to provide guidance for facility billing of surgical procedures and visits.

Response: The current APC structure and coding edits already do this. Payment for surgical procedures includes payment for all services related to the procedure (for example, postoperative care, preoperative valuation). Facilities may bill for visits in addition to surgical procedures when the visit is a separately identifiable service unrelated to the procedure. In such cases, the facilities attest to this by appending the –25 modifier to the line item for the visit.

Comment: One commenter said that CMS should provide guidance as to when it is appropriate to add together levels of service from two visits, and bill one visit at a higher level. Another commenter requested that CMS stop using the GO condition code in favor of the –27 modifier.

Response: We disagree. Each clinic visit should be coded separately. It is important to track utilization and for each clinic visit to be reported separately. This is critical for determining proper payment rates in the OPPS. Clinic visits should never be added together and billed as a single service with a higher level of service. We plan to continue using the GO modifier as it specifically addresses coding issues arising in the OPPS.

Comment: One commenter asked us to reconsider our G code descriptors for clinic and emergency visits.

Response: We will propose and finalize G code descriptors after we receive recommendations from an independent expert panel.

Comment: Several commenters asked us to develop guidelines based on a point or acuity system.

Response: The divergence of opinion in the hospital community makes it imperative that an independent expert panel be convened and that such a panel should make recommendations to CMS on these issues.

Comment: Several commenters were concerned about disparities between physician and facility coding for the same service. One commenter asked that hospitals be allowed to code a different level of service than the physicians.

Response: We do not believe that facilities and physicians would be expected to bill similar levels of service for the same encounter. The resources used by a facility for a visit may be quite different from the resources used by a physician for the same visit. Facilities should code a level of service based on facility resource consumption, not physician resource consumption. This includes situations where patients may see a physician only briefly, or not at all.

However, if a visit and another service is also billed (that is, chemotherapy, diagnostic test, surgical procedure) the visit must be separately identifiable from the other service because the resources used to provide non-visit services including staff time, equipment, supplies, and so forth, are captured in the line item for that service. Billing a visit in addition to another service merely because the patient interacted with hospital staff or spent time in a room for that service is inappropriate.

Comment: One commenter asked CMS to clarify proper billing for E/M services when a visit and another service, such as chemotherapy, have been provided.

Response: If a visit and another service is also billed (that is, chemotherapy, diagnostic test, or surgical procedure) the visit must be separately identifiable from the other

service. This is because the resources used to provide non-visit services (including staff time, equipment, supplies and so forth) are captured in the line item for that particular service. However, billing a visit in addition to another service—merely because the patient interacted with hospital staff or spent time in a room for that service—is inappropriate.

B. Observation Services

Coding and Billing Instructions

On November 30, 2001, we published a final rule updating changes to the OPPS for 2002. We implemented provisions that allow separate payment for observation services under certain conditions. That is, a hospital may bill for a separate APC payment (APC 0339) for observation services for patients with diagnoses of chest pain, asthma, or congestive heart failure when certain criteria are met. The criteria discussed in the November 30, 2001 final rule and as corrected in the March 1, 2002 final rule are also explained in detail in section XI of a Program Memorandum to intermediaries issued on March 28, 2002 (Transmittal A–02–026). Payment for HCPCS code G0244, observation care provided by a facility to a patient with congestive heart failure, chest pain or asthma, minimum eight hours, maximum 48 hours, was effective for services furnished on or after April 1, 2002.

Section XI of Transmittal A–02–026 that was issued on March 28, 2002, provides additional billing and coding instructions and requirements that flow from the basic criteria that we implemented in the November 30, 2001 and the March 1, 2002 final rules. Although we do not address them explicitly in the final rules, the additional instructions and requirements in Transmittal A–02–026 were developed to implement the basic observation criteria within the programming logic of the outpatient code editor (OCE), which is used to process claims submitted by hospitals for payment under the OPPS. For example, in the November 30, 2001 final rule, we state that an emergency department visit (APC 0610, 0611, or 0612) or a clinic visit (APC 0600, 0601, or 0602) must be billed in conjunction with each bill for observation services (66 FR 59879). In section XI of Transmittal A–02–026, we state that an E/M code (referred to, incorrectly, in Transmittal A–02–026 as an ''Emergency Management'' code), for the emergency room, clinic visit, or critical care is required to be billed on the day before or the day that the patient is admitted to observation. That is, unless one of the CPT codes assigned to APCs 0600, 0601, 0602, 0610, 0611, 0612, or 0620 is billed on the day before or the day that the patient is admitted to observation, separate payment for G0244 is not allowed. The codes assigned to these APCs are categorized by CPT as E/M codes. Although we did not include APC 0620, Critical Care, among the APCs that must be billed in order to receive separate payment for observation services, we added it in the program memorandum because critical care is an E/M service that can be furnished in a clinic or an emergency department. Critical care may appropriately precede admission to observation for chest pain, asthma, or congestive heart failure. We clarify in Transmittal A–02–026 that both the associated E/M code and G0244 are paid separately if the observation criteria are met. We also specify that the E/M code associated with observation must be billed on the same claim as the observation service.

Similarly, in the November 30, 2001 and the March 1, 2002 final rules, we require that certain diagnostic tests be performed in order to bill for separate payment for observation services. In Transmittal A–02–026, in section XI.B.2, we list the diagnostic tests that the OCE looks for on a bill for G0244. This list, which amplifies what we published in the November 30, 2001 and March 1, 2002 final rules, is incomplete and should read as follows to reflect the current OCE logic that is applied to claims for G0244:

- For chest pain, at least two sets of cardiac enzymes [either two CPK (82550, 82552, or 82553), or two troponin (84484 or 84512)], and two sequential electrocardiograms (93005);
- For asthma, a peak expiratory flow rate (94010) or pulse oximetry (94760, 94761, or 94762);
- For congestive heart failure, a chest x-ray (71010, 71020, or 71030) and an electrocardiogram (93005) and pulse oximetry (94760, 94761, or 94762).
- Note: Pulse oximetry codes 94760, 94761, and 94762 are treated as packaged services under the OPPS. Although no separate payment is made for packaged codes, hospitals must separately report the HCPCS code and a charge for pulse oximetry in order to establish that observation services for congestive heart failure and asthma diagnoses meet the criteria for separate payment.

Transmittal A–02–026 also provides specific coding instructions that hospitals must use when billing for observation services that do not meet the criteria for separate payment under APC 0339. In addition, Transmittal A–02–026 addresses the use of modifier –25 with the E/M code billed with G0244.

Comment: A few commenters requested clarification of the requirement that CPT 94010 (peak flow) be billed to establish a diagnosis of asthma. The commenter noted that CPT 94010 is the code for spirometry with recording and that it would be erroneous to bill peak flow, which is all that is relevant for asthma, as a spirometry, which requires a record and should include such elements as vital capacity and flow-volume loops. The commenter is concerned that we are instructing hospitals to bill incorrectly if our intention is solely to require peak flow.

Response: We are reviewing this comment and if we determine that a modification of the current requirement for peak flow is appropriate, we will revise the requirement in the program memorandum that implements the 2003 OPPS update effective January 1, 2003.

Comment: One commenter asked whether bedside services other than infusion, such as CVP placement, arterial punctures, and IV injections, can be billed when furnished to observation patients or whether these services are considered to be packaged into the observation payment.

Response: We would not expect that placement of a CVP line would be billed for a patient in observation. However, in general, any service that is separately payable under the OPPS, that is, procedures with status indicators S, X, K, G, V, or H, can be billed with G0244 and paid separately, although services with status indicator ''T'' (with the exception of Q0081), as we explain below, are *not* separately payable with G0244.

Direct Admissions to Observation

Since implementation of the provision for separate payment for observation services under APC 0339, a number of hospitals, hospital associations, and other interested parties have asked if separate payment for observation services would be allowed for a patient with chest pain, asthma, or congestive heart failure who is admitted directly into observation by order of the patient's physician but without having received critical care or E/M services in a hospital clinic or the emergency department on the day before or the day of admission to observation. We have responded during monthly CMS hospital open forum calls that, consistent with the criteria in the November 30, 2001 final rule, effective for services furnished on or after April

1, 2002, separate payment for observation services requires that an admission to observation be made by order of a physician in a hospital clinic or in a hospital emergency department. If a patient is directly admitted to observation but without an associated E/M service (including critical care) shown on the same bill, the hospital should bill observation services using revenue code 762 alone or revenue code 762 with one of the HCPCS codes for packaged observation services (CPT codes 99218, 99219, 99220, 99234, 99235, or 99236).

A related question has arisen in connection with a policy interpretation that was posted as a response to a ''Frequently Asked Question'' (FAQ) on our Web site on September 12, 2000. The FAQ follows:

''Q.97: If a patient is admitted from the physician's office to the observation room, will there be no reimbursement?

''A.97: Since observation is a packaged service, payment cannot be made if it is the only OPPS service on a claim. However, we believe that the ''admission'' of a patient to observation involves a low-level visit billed by the hospital, as well as whatever office visit the physician who arranged for the admission billed. Thus, when a patient arrives for observation arranged for by a physician in the community (that is, ''direct admit to observation''), and is not seen or assessed by a hospital-based physician, the hospital may bill a low-level visit code. This low-level visit code will capture the baseline nursing assessment, the creation of a medical record, the recording and initiation of telephone orders, and so forth. This visit may be coded only once during the period of observation. The observation charges should be shown in revenue code 762. The number of hours the patient was in observation status should be shown in the units field. Payment for those services is packaged into the APC for the visit. Other services performed in connection with observation, such as lab, radiology, and so forth, should be billed for as well. * * *''

We have been asked to clarify whether or not the low-level visit code suggested in the FAQ for patients directly admitted for observation services would satisfy the requirement that a line item for a hospital emergency visit, hospital clinic visit, or critical care appear on the same bill as HCPCS code G0244. Our response is that when we established the final criteria effective for services furnished on or after April 1, 2002, we did not contemplate that the low-level visit described in the FAQ would satisfy the requirement for the E/M code that a hospital must bill to show a hospital clinic visit or hospital emergency department visit was performed before observation services for asthma, congestive heart failure, or chest pain to bill and receive payment for G0244 under APC 0339.

In light of these questions, we have reviewed the criteria for separate payment for observation services under APC 0339, and we proposed to modify the criteria and coding for observation services furnished on or after January 1, 2003. Specifically, we proposed to create two new codes. These additional codes would allow us to collect data on the extent to which patients are directly admitted to hospital observation services without an associated hospital clinic visit or emergency department visit. The proposed codes were as follows:

G0LLL-Initial nursing assessment of patient directly admitted to observation with diagnosis of congestive heart failure, chest pain, or asthma.

G0MMM-Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain, or asthma.

If a hospital directly admits to observation from a physician's office a patient with a diagnosis of congestive heart failure, asthma, or chest pain, we proposed to require that G0LLL be billed with G0244. The current requirement that the hospital bill an emergency department visit (APC 0600, 0601, or 0602) or a clinic visit (APC 0610, 0611, or 0612) or a critical care service (APC 0620) in order to receive separate payment for observation services for patients not admitted directly from a physician's office would remain in effect. However, because the initial nursing assessment is part of any observation service, we proposed not to make separate payment for G0LLL. Rather, we proposed to assign status indicator ''N'' to G0LLL, to designate that charges submitted with G0LLL would be packaged into the costs associated with APC 0339. If G0LLL is billed, we would require that the medical record show that the patient was admitted directly from a physician's office for purposes of evaluating and treating chest pain, asthma, or congestive heart failure.

G0MMM describes the initial nursing assessment of a patient directly admitted to observation with a diagnosis other than chest pain, asthma, or congestive heart failure. We proposed to assign G0MMM for payment under APC 0706, New Technology—Level I. We proposed to require hospitals to bill G0MMM instead of the low level clinic visit referred to in the FAQ above to describe the initial nursing assessment of a patient directly admitted to observation with a diagnosis other than chest pain, asthma, or congestive heart failure. Separate payment would not be made for observation services billed with G0MMM. Rather, when billing G0MMM, hospitals would be required to use revenue code 762 alone or revenue code 762 with one of the HCPCS codes for packaged observation services (99218, 99219, 99220, 99234, 992335, or 99236). We proposed to create G0MMM to establish a separately payable code into which costs for observation care for patients directly admitted for diagnoses other than asthma, chest pain, or congestive heart failure can be packaged and recognized.

We would use billing data for G0LLL and G0MMM in reviewing the provisions for payment of observation services in future updates of the OPPS. In the proposed rule, we invited comment on the extent to which these codes address the concerns that have been raised in connection with patients who are directly admitted to observation services.

Comment: Everyone who commented on our proposed refinements of the requirements to enable separate payment for observation services supported the proposal to allow separate payment for patients admitted to observation directly from physicians' offices. However, the majority of commenters opposed the coding and payment methodology that we proposed to implement this change.

Commenters stated that having to use G0LLL and G0MMM, combined with the other requirements that have to be met in order to receive separate payment for observation of patients with asthma, congestive heart failure, and chest pain, would be burdensome and confusing, and would create operational inconsistencies and problems for hospitals. Several commenters urged CMS to simplify, the observation rules in order to reduce their complexity and lessen the burden they currently impose on hospitals. Some commenters were concerned that other payors might not accept the proposed new codes and that the codes would not be HIPAA compliant.

A number of commenters recommended alternatives to the establishment of G0LLL and G0MMM that would utilize information already being reported by hospitals on the UB–92 within the existing coding system for revenue centers, diagnoses, and source and type of admission. One commenter suggested a single G code for ''Intake into observation after outside evaluation'' supported by appropriate diagnosis coding and claims edits. One

commenter recommended instituting a ''per visit'' payment logic in the OCE and PRICER similar to that used for mental health and PHP services. Several commenters suggested returning observation to a time-based charging and coding methodology based on hours. Several commenters supported using existing E/M codes instead of creating new codes.

Response: We agree with many of the commenters that our proposal for direct admissions to observation seems administratively burdensome. However, we believe that the importance of creating a payment mechanism for direct admissions to observation outweighs the administrative burden at this time. We also believe it is vital that we be able to track the utilization of these services so we will have data upon which to base policy decisions in the future.

A number of the alternatives suggested by commenters are promising and merit further analysis and review. However, our preliminary inquiries revealed that most of the suggested alternatives would require systems changes that could take six months or longer to develop and install, and that such changes could not be implemented effective January 1, 2003. Therefore, we have decided to implement the proposed G codes as follows:

G0263, Direct admission of patient with diagnosis of congestive heart failure, chest pain or asthma for observation.

G0264, Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain, or asthma.

These codes would be HIPPA compliant. Other payers would make their own decisions about whether to use these codes for their own payment purposes.

Comment: One commenter asked that we instruct Fiscal Intermediaries to accept another revenue code in the 76X range for G0263 and G0264 because RC 762 may only be used to report observation charges.

Response: We are reviewing with our coding and claims processing experts to determine if there is a more appropriate revenue code to use when billing G0263 and G0264. We will provide specific instructions in the program memorandum issued to implement the January 2003 OPPS update.

Comment: Cancer centers urged CMS to expand the conditions for which we would make separate payment for observation to include febrile neutropenia, electrolyte disorders, chemotherapy hypersensitivity reaction, pulmonary embolisms, acute GI hemorrhage, and seizures presented by cancer patients under treatment at Cancer Centers. Other commenters suggested psychiatric conditions, acute abdominal pain, post-transplant threat of rejection, and pneumonia as appropriate for separate payment for observation.

Response: As we indicate in the November 30, 2001 final rule, we will review the indications for separately payable observation after we have acquired sufficient experience under the current system to make an informed decision as to whether an expansion is appropriate.

Comment: Most commenters asserted that our proposed payment for G0MMM for initial nursing assessment of a patient directly admitted to observation with a diagnosis other than chest pain, asthma, or congestive heart failure (APC 706) is too low and does not recognize the substantial type, level, and quality of the initial nursing services being provided. Commenters urged CMS either to set a higher payment rate for G0MMM or to allow an E/M code to be billed with G0MMM. Another commenter suggested assigning G0MMM to APC 0600 to be consistent with what CMS says in the FAQ 97. One commenter noted that it is inappropriate to assign G0MMM to a new technology APC because the code describes an E/M service, not a new technology service.

Response: We agree. We have therefore assigned G0264 for payment in APC 600, Low Level Clinic Visits.

Comment: One commenter wanted to know if G0LLL and G0MMM could be used for patients admitted from their homes, either (1) based solely upon a telephone call from the patient to the community physician and that physician's call to the hospital to order a direct admission for observation management, or (2) when directly admitted by the physician after going home following a visit to the physician's office, the patient's condition having deteriorated after seeing the physician.

Response: As long as the physician notifies the hospital that he/she is ordering the direct admission of the patient for observation and supports that order with the appropriate suspected diagnosis, we believe this would constitute a direct admission. Either G0263 or G0264 would be billed, depending on the final diagnosis supporting the direct admission observation services.

C. Billing Intravenous Infusions With Observation

Based on questions and concerns raised by hospitals since implementation of payment for APC 0339 effective April 1, 2002, we have also reviewed the current status of billing intravenous infusions with observation. Several hospitals have noted that claims for G0244 when billed with intravenous infusion services reported with HCPCS code Q0081 are denied because of the ''T'' status indicator assigned to HCPCS code Q0081. Our current payment rules for G0244 require that G0244 be denied if a service with status indicator ''T'' is performed the day before, the day of, or the day after observation care. Because patients in observation may require intravenous infusions of fluid, we proposed to create code G0EEE, Intravenous infusion during separately payable observation stay, per observation, payable under APC 0340 with status indicator ''X.'' When observation services that otherwise meet the billing requirements for separate payment under APC 0339 include an intravenous infusion administered as part of the observation care, G0EEE would be used to report the infusion service. We included instructions on the use of G0258 in the program memorandum issued to implement OPPS coding changes for the October 1, 2002 OCE. In the proposed rule, we solicited comment on the use of this code.

Comment: While appreciative of our recognizing the need for a mechanism that permits hospitals to bill for infusion therapy during observation, most commenters did not support our proposal to introduce a new code for the service. One commenter recommended terminating G0258 effective 12/31/02 because it creates operational burdens for the hospital and does not accurately reflect the resources used. Several commenters urged CMS to change the SI for APC 120 to which Q0081 is assigned to S. This would solve the problem and permit payment of Q0081 with G0244 and would also align the status indicators for the infusion of non-chemotherapy drugs with the infusion of chemotherapy drugs.

Commenters asked if CMS intends hospital to use G0258 instead of Q0081 when the infusion therapy is provided to the patient in the emergency department or clinic prior to patient's placement in observation when the observation stay ultimately qualifies for separate payment. The commenters pointed out that the hospital may not know when the patient is in the emergency department or clinic and the infusion therapy is initiated that the patient will subsequently be placed in an observation stay that qualifies for payment under G0244. Commenters

asked CMS to clarify how G0258 is to be used.

One commenter recommended, that we install an OCE edit to ignore Q0081 when checking for the presence of a procedure with SI=T.

Many commenters stated that the payment for G0248 should be the same as the payment for Q0081 because the resources expended for infusion therapy performed during a packaged observation stay are the same as those required for Q0081 furnished. These commenters disagreed with CMS's assertion that payment for G0258 should be discounted to equal 50 percent of the payment for Q0081 because Q0081 is invariably billed with a higher-paying procedure and is, therefore, discounted. Another commenter advocated adjusting the payment for G0244 to include the cost of infusion and eliminating a separate new code. The same commenter supported payment at 50 percent of the rate set for Q0081 because Q0081 would always be discounted because it is always billed with another procedure.

Response: Having reviewed the numerous concerns raised by commenters in connection with the use of HCPCS code G0258, Intravenous infusion during separately payable observation stay, per observation stay (must be reported with G0244), and our proposed payment for G0258, we agree with commenters that requiring the use of this code is problematic. We have determined that the OCE logic can be modified to allow payment for G0244, even though Q0081 is assigned to an APC with status indicator T. Therefore, effective for services furnished on or after January 1, 2003, we are withdrawing G0258. Instead hospitals may submit claims for G0244 with Q0081 when infusion therapy is provided, and the claim will be paid if all other requirements and conditions are met. The status indicator for G0081 will not change.

Annual Update of ICD–9 Diagnosis Codes

To receive payment for G0244, we require hospitals to bill specified ICD–9–CM diagnosis code(s). Because ICD–9–CM codes are updated effective October 1 of each year, we proposed to issue by Program Memorandum any changes in the diagnosis codes required for payment of G0244 resulting from the ICD–9–CM annual update.

In the March 1, 2002 final rule (67 FR 9559) and in Transmittal A–02–026 issued on March 28, 2002, we listed the diagnosis codes required in order for separate payment of observation services under APC 0339 to be made for patients with congestive heart failure. We added by program memorandum the following new ICD–9–CM codes to the list of allowed diagnosis codes for separate payment for observation of patients with congestive heart failure, effective for services furnished on or after October 1, 2002:

428.20 Unspecified systolic heart failure
428.21 Acute systolic heart failure
428.22 Chronic systolic heart failure
428.23 Acute on chronic systolic heart failure
428.30 Unspecified diastolic heart failure
428.31 Acute diastolic heart failure
428.32 Chronic diastolic heart failure
428.33 Acute on chronic diastolic heart failure
428.40 Unspecified combined systolic and diastolic heart failure
428.41 Acute combined systolic and diastolic heart failure
428.42 Chronic combined systolic and diastolic heart failure
428.43 Acute on chronic combined systolic and diastolic heart failure

In the August 9, 2002 proposed rule, we invited comment on the addition of these diagnosis codes to the criteria for separate payment for observation services under APC 0339.

Comment: One commenter recommended adding the following codes to the list of diagnoses for asthma: 493.00, 493.10, 493.20, and 493.90

Response: We are not including these diagnoses because they would not be appropriate for use with patients requiring observation services because they are experiencing acute exacerbations of asthma.

- Effective for services furnished on or after January 1, 2003, hospitals may bill for patients directly admitted for observation services using the following codes:

G0263, Direct admission of patient with diagnosis of congestive heart failure, chest pain or asthma for observation.

G0264, Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain, or asthma.

- Payment for G0264 will be made under APC 600.
- Payment for G0263 will be packaged into the payment for APC 339
- Payment for G0244 will be allowed when billed with Q0081, Infusion therapy other than chemotherapy, when furnished to patients with asthma, congestive heart failure, or chest pain, subject to all other conditions for payment having been met.

C. Payment Policy When a Surgical Procedure on the Inpatient List Is Performed on an Emergency Basis

As we state in section II.B.5 of this preamble, the inpatient list specifies those services that are only paid when provided in an inpatient setting. The inpatient list proposed for 2003 is printed as Addendum E. In Addendum B, status indicator C designates a HCPCS code that is on the inpatient list.

Over the past year, some hospitals and hospital associations have asked how a hospital could receive Medicare payment for a procedure on the inpatient list that had to be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition who was transferred or died before being admitted as an inpatient. We reviewed within the context of our current policy the cases brought to our attention for which payment under the OPPS was denied because a procedure with status indicator C was on the bill. Based on that review, we proposed to clarify our policy regarding Medicare payment when a procedure with status indicator C is performed under certain life-threatening, emergent conditions. In the proposed rule, we solicited comments on the extent to which the payment policy described below addresses hospitals' concerns. We stated it would be most helpful if commenters provided specific examples of cases when hospitals have, in these instances, submitted bills for a procedure with OPPS status indicator C that were not paid.

1. Current Policy

In the April 7, 2000 final rule (65 FR 18451), in response to comments about the appropriate level of payment for patients who die in the emergency department, we set forth the following guidelines for fiscal intermediaries to use in determining how to make payment when a patient dies in the emergency department or is sent directly to surgery and dies there.

- If the patient dies in the emergency department, make payment under the outpatient PPS for services furnished.
- If the emergency department or other physician orders the patient to the operating room for a surgical procedure, and the patient dies in surgery, payment will be made based on the status of the patient. If the patient had been admitted as an inpatient, pay under the hospital inpatient PPS (a DRG-based payment).
- If the patient was not admitted as an inpatient, pay under the outpatient PPS (an APC-based payment).
- If the patient was not admitted as an inpatient and the procedure is

designated as an inpatient-only procedure (payment status indicator C), no Medicare payment will be made for the procedure, but payment will be made for emergency department services.

The OPPS outpatient code editor (OCE) currently has an edit in place that generates a ''line item denial'' for a line on a claim that has a status indicator C. A line item denial means that the claim can be processed for payment but with some line items denied for payment. A line item denial can be appealed under the provisions of section 1869 of the Act. The OCE includes another edit that denies all other line items furnished on the same day as a line item with a status indicator C. The rationale for this edit is that all line items for services furnished on the same date as the procedure with status indicator C would be considered inpatient services and paid under the appropriate DRG.

As part of the definition of line item denial in the program memorandum that we issue quarterly to update the OCE specifications (for example, see Program Memorandum/Intermediaries, Transmittal A–02–052, June 18, 2002, which is available on our Web site at *http://cms.hhs.gov/manuals/pm_trans/A02052.pdf*), we state that a line item denial cannot be resubmitted except for an emergency room visit in which a patient dies during a procedure that is categorized as an inpatient procedure: ''Under such circumstances, the claim can be resubmitted as an inpatient claim.''

In Addendum D of the March 1, 2002 final rule, we designate payment status indicator ''C'' as follows: ''Admit patient; bill as inpatient.''

2. Hospital Concerns

Hospitals have requested clarification regarding billing and payment in certain situations that our current policy does not seem to explicitly address. The following scenarios synthesize cases described by hospitals for which they have encountered problems when billing for a procedure with status indicator C.

Scenario A: A procedure assigned status indicator C under the OPPS is performed to resuscitate or stabilize a beneficiary who appears with or suddenly develops a life-threatening condition. The patient dies during surgery or postoperatively before being admitted.

Scenario B: An elective or emergent surgical procedure payable under the OPPS is being performed. Because of sudden, unexpected intra-operative complications, the physician must alter the surgical procedure and perform a procedure with OPPS status indicator C. The patient dies during the operation before he or she is admitted as an inpatient.

Scenario C: A procedure with status indicator C is performed to resuscitate or stabilize a beneficiary who appears with or suddenly develops a life-threatening condition. After the procedure, the patient is transferred to another facility for postoperative care.

3. Clarification of Payment Policy

We proposed the following policy for fiscal intermediaries and providers to use in determining the appropriate Medicare payment in cases such as those described in the section above.

A procedure assigned status indicator C under the OPPS is never payable under the OPPS. Therefore, for a hospital to receive payment when a procedure with OPPS status indicator C is performed and: (1) The patient dies during or after the procedure, before being admitted, or (2) the patient survives the procedure and is transferred following the procedure, the patient's medical record must contain all of the following information:

- Either orders to admit written by the physician responsible for the patient's care at the hospital to which the patient was to be admitted following the procedure for the purpose of receiving inpatient hospital services and occupying an inpatient bed, or written orders to admit and transfer the patient to another hospital following the procedure.
- Documentation that the reported HCPCS code for the surgical procedure with OPPS payment status indicator C (such as CPT code 61345) was actually performed.
- Documentation that the reported surgical procedure with status indicator C was medically necessary.
- If the patient is admitted and subsequently transferred to another facility, documentation that the transfer was medically necessary, such as the patient requiring postoperative treatment unavailable at the transferring facility.

In the case of a patient who dies during performance of a procedure with OPPS status indicator C before being admitted, the hospital would submit a claim for all services provided, including a line item for the status indicator C procedure. The claim would be rejected for payment under the OPPS and returned to the hospital. The hospital would resubmit the claim for payment as an inpatient stay under the appropriate DRG.

In the case of a patient who is admitted and transferred, the transferring hospital would be paid a per diem DRG rate if all the above conditions are met. (We proposed to revise § 3610.5 of the Medicare Intermediary Manual accordingly.) Because these services would be paid according to the appropriate DRG or per diem (see below), all services that were furnished before admission that would otherwise be payable under the OPPS would be paid in accordance with the provisions of § 3610.3 of the Medicare Intermediary Manual (''3-day rule'') and § 415.6 of the Medicare Hospital Manual.

Note that a physician's order to admit a patient to an observation bed following a procedure designated with OPPS status indicator C would not constitute an inpatient admission and, therefore, would not qualify the procedure with status indicator C for payment. In this instance, the only allowable Medicare payment would be for a code payable under APC 0610, 0611, or 0612 if those services were provided. Payment would not be allowed for either the procedure with status indicator C or for any ancillary services furnished on the same date.

Comment: Commenters agreed that the current policy on billing and payment when procedures on the inpatient list are performed on an outpatient basis requires clarification and modification. However, commenters stated that our proposals, if implemented, would be burdensome and create extra work for hospitals. Commenters opposed our proposal that an outpatient claim be submitted for rejection and then resubmitted as an inpatient claim. Commenters asserted that this would be unwieldy and create an unacceptable delay in payment. Many commenters were concerned that it would be difficult to expect a physician to write an order to admit a patient who expired during emergency surgery, and that asking physicians to do so to satisfy a billing requirement would not be appropriate. Some commenters were concerned that submitting an inpatient claim that is inconsistent with medical records documentation could create problems with medical review. However, commenters did not provide illustrations of actual cases when hospitals have submitted outpatient bills for a procedure with status indicator C that was performed in an emergency situation and not paid which would have added specificity to the general comments.

Commenters offered several alternatives to our proposal. Several commenters suggested that these cases be initially billed as inpatient stays,

supported by documentation that the procedure was performed and was medically necessary, and that a presumption of admission be made for payment purposes. Several commenters suggested that a reduced DRG-related amount be established as payment in these special cases. Several commenters suggested the use of a condition code that would allow submission of an outpatient claim when procedures on the inpatient list are performed in emergency situations.

Response: We appreciate commenters' reactions and suggestions of ways to make payment under the OPPS in emergency situations when procedures on the inpatient list are performed on a beneficiary who is not admitted as an inpatient. After careful review and consideration of the comments and recommendations, we have decided to modify certain aspects of our proposed policy, while retaining certain others. We are also taking steps to ensure that OCE edits are consistent with our policy.

The underlying principle is our policy that procedures on the inpatient list performed on patients whose status is that of outpatient are not payable as outpatient services.

However, we recognize that there are occasions when a procedure on the inpatient list must be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition whose status is that of an outpatient. To receive payment in those cases, hospitals admit the patient and submit an inpatient claim.

In cases where a procedure on the inpatient list must be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition whose status is that of an outpatient, the patient may be admitted and transferred to another hospital. In these cases, the transferring hospital is paid a per diem DRG rate. We shall revise section 3610.5 of the Medicare Intermediary Manual to reflect this policy.

On rare occasions, a procedure on the inpatient list must be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition whose status is that of an outpatient and the patient dies before being admitted as an inpatient. For those rare and unusual cases, we are instructing hospitals to submit an outpatient claim for all services furnished, including the procedure code with status indicator C to which a new modifier is attached. The exact modifier that is to be used in these cases had not been issued by the HCPCS alpha-numeric workgroup in time for publication in this final rule. The modifier and instructions for its use will be included in the program memorandum for the January 2003 update. We believe that such patients would typically receive services such as those provided during a high-level emergency visit, appropriate diagnostic testing (X-ray, CT scan, EKG, and so forth), and administration of intravenous fluids and medication prior to the surgical procedure. Because these combined services constitute an episode of care, we will pay claims with a procedure code on the inpatient list that are billed with the new modifier under new technology APC 977. Separate payment will not be allowed for other services furnished on the same date. This approach allows hospitals to submit an outpatient claim and receive payment without additional paperwork, it results in consistency between the medical record and patient status, and it allows us to collect data on the costs associated with these very unusual and infrequent cases for future use in updating the OPPS.

Procedures with status indicator C but without the new modifier that are submitted on an outpatient bill will receive a line item denial, and no other services furnished on the same date are payable.

If an outpatient has a procedure that is on the inpatient list performed, and is subsequently admitted to an observation bed, the procedure with status indicator C submitted on an outpatient bill will receive a line item denial. Further, we have decided not to make final our proposal to make payment for APC 610, 611 or 612 under such circumstances. Rather, in such cases no other services furnished on the same date are payable.

We did not receive any comments on the documentation that we proposed to require in the patient's medical record when a procedure with status indicator C is performed and: (1) The patient dies before being admitted as an inpatient, or (2) the patient survives the procedure and is admitted and transferred. Therefore, we are making those requirements final.

4. Orders To Admit

Some hospitals have raised questions about the timing of a physician's order to admit a patient. The requirements for authenticating physician orders and the standards for medical record keeping fall outside the scope of this rule and OPPS payment policy. The payment provisions that we are making final in this rule are to assist hospitals and contractors in determining how to bill and pay for services appropriately under Medicare. The patient's admission status, as documented by the medical records, determines what Medicare payment is appropriate. Medical record keeping and documentation requirements are addressed in the Medicare hospital conditions of participation at § 482.24, and are governed by applicable State law and State licensing rules and hospital accreditation standards.

Comment: A few commenters requested clarification on what is meant by ''admit'' and the documentation that CMS would expect to see in order to substantiate that a patient was admitted as an inpatient. One commenter expressed concern about the variability in fiscal intermediaries' policies regarding the changing of an admission status after the service has been provided.

Response: As we have indicated, these issues are addressed in the Medicare hospital conditions of participation at § 482.24, and are governed by applicable State licensing rules and hospital accreditation standards. Questions and concerns related to these issues should be addressed to the parties who are responsible for these rules, regulations, and standards.

When a procedure on the inpatient list must be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition whose status is that of an outpatient and the patient dies before being admitted as an inpatient, the hospital should submit an outpatient claim for all services furnished, including the procedure with status indicator C to which a new modifier, which will be announced by program memorandum is attached. Claims with a procedure code on the inpatient list that are billed with the new modifier will be paid under APC 977.

We are making final the requirement that information specified in the proposed rule be included in the medical record to support payment when a procedure with status indicator C is performed on an outpatient and the patient dies or is admitted and transferred.

D. Status Indicators

The status indicators we assign to HCPCS codes and APCs under the OPPS have an important role in payment for services under the OPPS because they indicate if a service represented by a HCPCS code is payable under the OPPS or another payment system and also if particular OPPS policies apply to the code. We are providing our status indicator assignments for APCs in Addendum A, HCPCS codes in

Addendum B, and definitions of the status indicators in Addendum D.

The OPPS is based on HCPCS codes for medical and other health services. These codes are used for a wide variety of payment systems under Medicare, including, but not limited to, the Medicare fee schedule for physician services, the Medicare fee schedule for durable medical equipment and prosthetic devices, and the Medicare clinical laboratory fee schedule. For purposes of making payment under the OPPS, we need a way to signal the claims processing system which HCPCS codes are paid under the OPPS and those codes to which particular OPPS payment policies apply. We accomplish this identification in the OPPS through the establishment of a system of status indicators with specific meanings. Addendum D defines the meaning of each status indicator for purposes of the OPPS.

We assign one and only one status indicator to each APC and to each HCPCS code. Each HCPCS code that is assigned to an APC has the same status indicator as the APC to which it is assigned.

Specifically, in 2003, we proposed to use the status indicators in the following manner:

- ''A'' to indicate services that are paid under some payment method other than OPPS, such as the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule or the physician fee schedule. Some but not all—of these other payment systems are identified in Addendum D.
- ''C'' to indicate inpatient services that are not payable under the OPPS.
- ''D'' to indicate a code that was deleted effective with the beginning of the calendar year.
- ''E'' to indicate services for which payment is not allowed under the OPPS or that are not covered by Medicare.
- ''F'' to indicate acquisition of corneal tissue, which is paid at reasonable cost.
- ''G'' to indicate drugs and biologicals that are paid under OPPS transitional pass-through rules.
- ''H'' to indicate devices that are paid under OPPS transitional pass-through rules.
- ''K'' to indicate drugs and biologicals (including blood and blood products) and certain brachytherapy seeds that are paid in separate APCs under the OPPS, but that are not paid under OPPS transitional pass-through rules.
- ''N'' to indicate services that are paid under the OPPS for which payment is packaged into another service or APC group.
- ''P'' to indicate services that are paid under the OPPS but only in partial hospitalization programs.
- ''S'' to indicate significant procedures that are paid under OPPS but to which the multiple procedure reduction does not apply.
- ''T'' to indicate significant services that are paid under the OPPS and to which the multiple procedure payment discount under OPPS applies.
- ''V'' to indicate medical visits (including clinic or emergency department visits) that are paid under the OPPS.
- ''X'' to indicate ancillary services that are paid under the OPPS.

The software that controls Medicare payment looks to the status indicators attached to the HCPCS codes and APCs for direction in the processing of the claim. Therefore, the assignment of the status indicators has significance for the payment of services. We sometimes change these indicators in the course of a year through program memoranda. Moreover, indicators are established for new codes that we establish in the middle of the year, either as a result of a national coverage decision or otherwise. A status indicator, as well as an APC, must be assigned so that payment can be made for the service identified by the new code.

Our proposed status indicators identified for each HCPCS code and each APC appear in Addenda A and B of the proposed rule. We requested comments on the appropriateness of the indicators we have assigned.

We received several comments on this proposal, which are summarized below:

Comment: Some commenters said that our proposed payment for influenza and pneumococceal pneumonia vaccines and orphan drugs were inadequate to ensure the provision of these drugs and biologicals.

Response: As discussed in section III.B, we will pay reasonable cost for these drugs and biologicals in 2003. Therefore, we have assigned orphan drugs a status indicator of F and have redefined the status indicator F to mean that the item or service is paid on a reasonable cost basis. Until now, only corneal tissue acquisition has been paid as reasonable cost under OPPS and, therefore, the status indicator was specific to corneal tissue. However, beginning January 1, 2003, the ''F'' status indicator will apply to any item or service paid at reasonable cost.

With regard to influenza and pneumococcal pneumonia vaccine, which we will also pay on a reasonable cost basis, effective January 1, 2003, we have created a new status indicator ''L'' ''Influenza vaccine; pneumococcal pneumonia vaccine'' to indicate that these vaccines are paid on a reasonable cost basis but deductible and coinsurance do not apply to the payment. We show the new status indicator in Addendum D and we show it for these services in Addendum B. We are doing the following:

- Redefining status F to indicate an item or service that is paid on a reasonable-cost basis.
- Changing the status indicator for influenza and pneumococceal pneumonia vaccines to status indicator L and change orphan drugs to status indicator F.
- Changing the status indicator for APC 225 to S.

E. Other Policy Issues Relating to Pass-Through Device Categories

1. Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

In the November 30, 2001 final rule, we explained the methodology we used to estimate the portion of each APC rate that could reasonably be attributed to the cost of associated devices that are eligible for pass-through payments (66 FR 59904). Effective with implementation of the 2002 OPPS update on April 1, 2002, we deduct from the pass-through payments for those devices an amount that offsets the portion of the otherwise applicable APC payment amount that we determined is associated with the device, as required by section 1833(t)(6)(D)(ii) of the Act. In the March 1, 2002 final rule, we published the applicable offset amounts for 2002, which we had recalculated to reflect certain device cost assignments that were corrected in the same final rule (67 FR 9557).

For the 2003 OPPS update, we proposed to estimate the portion of each APC rate that could reasonably be attributed to the cost of an associated pass-through device that is eligible for pass-through payment using claims data for services furnished between July 1, 2001, through December 31, 2001. We proposed to use only the last 6 months of 2001 claims data because bills for pass-through devices submitted during this time period would use only device category codes, allowing a more consistent analysis than would result were we to include pre-July 1 claims that might still show item-specific codes for pass-through devices. Using these claims, we would calculate a median cost for every APC without packaging the costs of associated C-codes for device categories that were billed with the APC. We would then calculate a median cost for every APC with the

costs of associated C-codes for device categories that were billed with the APC packaged into the median. Dividing the median APC cost minus device packaging by the median APC cost including device packaging would allow us to determine the percentage of the median APC cost that is attributable to associated pass-through devices. By applying these percentages to the APC payment amount, we would determine the applicable offset amount. Table 11 shows the offsets that we applied in 2003 to each APC that contains device costs. APCs were included for offsets if their device costs comprised at least 1 percent of the APC's costs. (However, if any APC's calculated offset had been less than 1 dollar, that APC and offset would not have been included.)

For this final rule, we used the device data for the 12 months ended March 31, 2002 to calculate the device and non-device portions of APCs median costs. We began with the same APCs that were listed on Table 9 of our proposed rule, with two additions. We added APCs 0648 and 0651, because they showed appreciable device percentages using our methodology. We again applied these percentages to the APC payment amounts and excluded any APC's percentage of device costs less than one percent and calculated offset amounts less than one dollar.

We received some comments on this proposal, which are summarized below:

Comment. A commenting party contended that our list of device offsets in our proposed rule is incorrect since it includes many computed offsets to APC payments for devices that will no longer receive pass-through payments. The commenter recommended that we exclude the offsets of all devices in categories that are bundled, since there is no separate pass-through payment to be offset.

Response. The offset list is a list of potential offsets. We, of course, do not know in advance which procedures and APCs will be mapped into new categories as the new categories are created and become effective. Yet, we are required to subtract the amount of similar devices in pass-through payment under section 1833(t)(6)(D)(ii) of the Act. Therefore, for the proposed rule, we calculate the device costs in each APC and include APCs on the offset list if their device costs were at least 1 percent of the APC's cost. We use a similar list for this final rule.

Comment. One commenter expressed concern about the difference in offset amounts proposed for APC 0107, Insertion of Cardioverter-Defibrilator, and APC 0108, Insertion/Replacement/Repair of Cardioverter-Defibrilator Leads. The commenter wondered why, when the cost of the cardioverter-defibrilator is 2 to 3 times the cost of the leads, the offset amount for APC 0107 is less than the offset amount for APC 0108.

Response. The commenter is incorrect that we proposed an offset amount for 0107 (83.18 percent) that is less than for 0108 (82.18 percent). Moreover, the commenter mistakenly believes that APC 0107 is for insertion/replacement/repair of cardioverter-defibrilator leads when, in fact, the definition of CPT code 33249 (the only CPT code in APC 0108) is ''Insertion or repositioning of electroleads for single or dual chamber pacing cardioverter-defibrilator and insertion of pulse generator.'' Hence, CPT code 33249 is for the insertion of a pulse generator and insertion or repositioning of leads. It is not, as the commenter indicates, for insertion or repositioning of leads alone. As shown in Table 11, the offset percent for APC 0107 is 93.29 and the offset percent for APC 0108 is 92.99.

Comment. A commenting party contended that the offsets appear to be computed using departmental cost-to-charge ratios (CCRs), yet pass-through payments for devices were computed using an overall hospital CCR. The party contended that in cases in which the hospital CCR is higher than the departmental CCR, there is effectively a zero pass-through payment for devices. Therefore, the party recommended that the offsets should be calculated using the same CCRs used to compute pass-through payments.

Response: Although the commenter states that calculating a device pass-through payment using a hospital CCR that is higher than the departmental CCR used to determine the applicable offset amount results in effectively no payment for a device, it appears to us that the opposite result would occur. That is, in the situation described, a lower offset amount would be applied to a higher calculated device cost, resulting in a higher net device payment. Offset amounts represent device costs that are included in the median costs of a procedure. The median cost of the procedure is determined, as we determine median costs for all services, by totaling all the procedure's component costs calculated using department-specific CCRs. We use department-specific CCRs to calculate the cost of the procedure, which includes devices, and because offsets are intended to represent the cost of devices that are included in the cost of the procedure, we believe the same departmental-CCR method must be applied in calculating offsets.

TABLE 11.—OFFSETS TO BE APPLIED FOR EACH APC THAT CONTAINS DEVICE COSTS

APC	Description	APC percent attributed to devices	Device related costs to be subtracted from pass-through payment
0032	Insertion of Central Venous/Arterial Catheter	31.96	$191.22
0048	Arthroplasty with Prosthesis	29.92	633.96
0051	Level III Musculoskeletal Procedures Except Hand and Foot	1.31	22.48
0052	Level IV Musculoskeletal Procedures Except Hand and Foot	3.08	65.48
0080	Diagnostic Cardiac Catheterization	10.63	195.69
0081	Non-Coronary Angioplasty or Atherectomy	31.45	713.58
0082	Coronary Atherectomy	48.25	2,174.88
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	29.59	802.06
0085	Level II Electrophysiologic Evaluation	37.00	805.10
0086	Ablate Heart Dysrhythm Focus	41.96	1,156.01
0087	Cardiac Electrophysiologic Recording/Mapping	51.40	1,056.10
0088	Thrombectomy	3.80	64.56
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	77.40	4,543.29
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	77.14	4,942.78
0090	Insertion/Replacement of Pacemaker Pulse Generator	79.61	3,782.34
0654	Insertion/Replacement of a permanent dual chamber pacemaker	78.27	3,749.52

TABLE 11.—OFFSETS TO BE APPLIED FOR EACH APC THAT CONTAINS DEVICE COSTS—Continued

APC	Description	APC percent attributed to devices	Device related costs to be subtracted from pass-through payment
0091	Level II Vascular Ligation	1.08	15.04
0653	Vascular Reconstruction/Fistula Repair with Device	10.83	169.60
0104	Transcatheter Placement of Intracoronary Stents	46.65	1,862.31
0105	Revision/Removal of Pacemakers, AICD, or Vascular	4.60	44.61
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	50.46	1,442.72
0107	Insertion of Cardioverter-Defibrillator	93.29	15,871.30
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	92.99	21,509.86
0109	Removal of Implanted Devices	1.61	6.27
0115	Cannula/Access Device Procedures	25.85	327.87
0119	Implantation of Devices	74.37	3,463.86
0122	Level II Tube Changes and Repositioning	40.26	225.62
0124	Revision of Implanted Infusion Pump	52.73	1,377.33
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	2.87	26.21
0152	Percutaneous Abdominal and Biliary Procedures	31.57	165.11
0652	Insertion of Intraperitoneal Catheters	10.91	160.05
0154	Hernia/Hydrocele Procedures	2.73	36.63
0167	Level III Urethral Procedures	43.96	649.32
0168	Level II Urethral Procedures	1.15	14.67
0179	Urinary Incontinence Procedures	56.34	3,066.24
0182	Insertion of Penile Prosthesis	58.45	2,908.45
0202	Level VIII Female Reproductive Proc	38.35	911.22
0222	Implantation of Neurological Device	88.08	10,461.01
0223	Implantation of Pain Management Device	52.96	1,133.11
0225	Implantation of Neurostimulator Electrodes	81.03	5,888.13
0226	Implantation of Drug Infusion Reservoir	82.74	6,228.55
0227	Implantation of Drug Infusion Device	81.57	6,147.49
0229	Transcatheter Placement of Intravascular Shunts	63.65	1,907.33
0246	Cataract Procedures with IOL Insert	1.38	16.00
0259	Level VI ENT Procedures	84.07	16,118.86
0279	Level II Angiography and Venography except Extremity	2.18	9.83
0280	Level III Angiography and Venography except Extremity	4.89	38.80
0297	Level II Therapeutic Radiologic Procedures	1.35	5.41
0651	Complex Interstitial Radiation Source Application	85.13	2,429.25
0670	Intravenous and Intracardiac Ultrasound	53.75	847.71
0680	Insertion of Patient Activated Event Recorders	77.72	2,275.14
0681	Knee Arthroplasty	64.16	4,945.63
0686	Level III Skin Repair	37.79	280.72
0687	Revision/Removal of Neurostimulator Electrodes	35.06	472.51
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	69.42	2,699.74
0648	Breast Reconstruction with Prosthesis	31.69	740.32

2. Devices Paid With Multiple Procedures

As explained above, under section 1833(t)(6)(D)(ii) of the Act, the amount of additional payment for a device eligible for pass-through payment is the amount by which the hospital's cost exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. Thus, for devices eligible for pass-through payment, we reduce the pass-through payment amount by the cost attributable to the device that is already packaged into the APC payment for an associated procedure. For 2002, we developed offset amounts for 59 APCs (March 1, 2002 final rule, 67 FR 9556 through 9557, Table 1).

In our November 30, 2001 final rule (66 FR 59856), we articulated a policy regarding the calculation of the offsets for device costs already reflected in APCs in cases where the payment for the associated APC is reduced due to the multiple procedure discount. The policy was in response to several commenting parties that recommended that we apply the multiple procedure discount only to the non-device-related portion of the APC payment amount (66 FR 59906).

We agreed with the commenters that the full pass-through offset should not be applied when the APC payment is subject to the multiple procedure discount of 50 percent.

The purpose of the offset is to ensure that the OPPS is not making double payments for any portion of the cost associated with the use of the pass-through item. We stated in the November 30, 2001 rule that the offset should reflect that portion of the cost for the pass-through device actually reflected in the payment that is received for the associated APC. We consequently ruled that the most straightforward methodology for applying this principle is to reduce the amount of the offset amount by 50 percent whenever the multiple procedure discount applies to the associated APC. This discounting of the offset is applied in 2002 to bills subject to multiple procedure discounting that also include devices eligible for pass-through payment.

The significant number of device categories that are expiring in 2003 combined with our proposal to package 100 percent of device costs into their associated APCs has prompted us to revisit the current policy of reducing offsets for pass-through devices in instances when multiple procedure discounts are applied to procedures

associated with pass-through device categories. In order to determine the impact of multiple procedure discounting on APCs with full packaging of device costs, we reviewed the median costs of all APCs after incorporation of device costs and arrayed them in order of descending median cost. We also determined the contribution (in absolute dollars and as a percentage) of device costs to the median costs of each APC.

We then determined which APCs containing devices would be billed together. We next determined, based on median cost data, which device containing APCs would be subject to the 50 percent multiple procedure reduction. After identifying these APCs, we applied a 50 percent reduction to arrive at a discounted payment amount. We then reviewed the contribution of device costs to the discounted APC both as a percentage and in absolute dollars to determine if applying the 50 percent reduction would result in underpayment for the service. We determined that the reduced payment was adequate to pay both for the devices incorporated into the APC and for the procedure cost in the context of performing multiple procedures. We obtained the same results even when we overstated device costs in our model by 5 or 10 percent to offset concerns expressed by some manufacturers and physicians that hospital charges for transitional pass-through devices may be understated.

We noted that almost all APCs with high device costs (such as insertion of pacemakers, insertion of cardioverter-defibrillators, insertion of infusion pumps and neurostimulator electrodes) would never be subject to a multiple procedure discount. They have the highest relative weights in the OPPS, and we would not expect these procedures to be performed during the same operative session with a higher paying procedure with status indicator ''T.'' Therefore, we proposed to continue our current policy of multiple procedure discounting. That is, when two or more APCS with status indicator ''T'' are billed together we proposed to pay 100 percent for the highest cost APC and 50 percent for all other APCs with status indicator ''T.'' We proposed not to adjust these payments to account for device costs in the APCs.

We received a large number of comments on this proposal, which are summarized below:

Comment: Many commenters asked that the status indicator be changed from ''T'' to ''S'' for APCs for which a large amount of the cost of the APC is cost for a device that is packaged into the APC. They said that it is not appropriate to apply the multiple procedure discount that is applied to services with status indicator ''T'' to APCs for which the cost of a device is the majority of the cost of the APC because there is no efficiency in the provision of multiple devices. They said that the multiple procedure discount should only apply to the nondevice portion of the APC payment.

Response: We reviewed the data for combinations of APCs billed on the same claim and determined that it would not be typical for an APC, which is predominantly device cost, to be the second or subsequent APC on the same claim. Hence, it would not be typical that the predominantly device APC would be reduced (because a predominantly device APC would generally be the highest cost APC on the claim).

In the case of APC 225, however, we did change the status indicator to ''S'' because we were convinced that it must be performed when APC 222 also performed and that, therefore, a status indicator of ''T'' would not result in appropriate payment for 225.

Comment: A number of commenters took issue with our claim that almost all APCs with high device costs (such as insertion of pacemakers, insertion of cardioverter-defibrillators, insertion of infusion pumps, and neurostimulator electrodes) would never be subject to a multiple procedure discount. They asserted that some high cost APCs do incur multiple procedure discounting. The example most provided is the implantation of a neurostimulator (APC 0222) with neurostimulator electrodes or leads (APC 0225). They said that the multiple procedure discount along with proposed payment cuts to these APCs even more significantly impact the payment of these services and warrant extensive review, analysis, and consideration of outside data. They also recommended that we change the status indicators for these procedures to ''S'' (significant procedure), which are not reduced when performed as a multiple procedure in the same session. Other examples cited were: bilateral neurostimulator implants for patients with Parkinson's disease (APC 0222) and implantation of a spinal infusion pump, which involves implantation of a catheter (APC 0223) and infusion pump (APC 0227) and dual implantation of an artificial urinary sphincter and a penile prosthesis in prostate cancer survivors. One commenter recommended that all device-related APCs have a status indicator of ''S'' to reflect significant resources.

Response: We continue to believe that most procedures with significant device costs packaged in will, if provided on the same day and billed in conjunction with another procedure, be the most expensive procedure on the claim and thus not subject to discounting. We are concerned that, if we were to discontinue our policy of reducing payment for multiple procedures, we would overpay some lower valued procedures. We received many thoughtful comments on the multiple procedure discounting of certain APCs and we intend to take these comments under advisement and study this issue further.

Comment: One commenter objected to our proposal to stop applying the 50 percent discount to offsets to pass-through payments when there are multiple procedures involving a claim of a pass-through device also.

Response: As discussed above, the discount to offsets to pass-through payments will become a much less significant aspect beginning January 1, 2003, when we will retire 95 of 97 existing categories and add a limited number of new categories.

F. Outpatient Billing for Dialysis

Currently, Medicare does not pay for dialysis treatments furnished to End-Stage Renal Disease (ESRD) patients on an outpatient basis, unless the hospital also has a certified hospital-based ESRD facility. As a result of this policy, ESRD patients in need of emergency dialysis have been admitted to the hospital. These admissions have been found to be inappropriate by the Quality Improvement Organizations, and payment has been denied.

When ESRD patients come to the hospital for a medical emergency or for problems with their access sites, they typically miss their regularly scheduled dialysis appointments. If the ESRD patient's usual facility is unable to reschedule the dialysis treatment, the ESRD patient has to wait until the next scheduled dialysis appointment. We are concerned that by maintaining this policy, ESRD patients may be receiving interrupted care because there will be unnecessary lapses in treatment. The ESRD patient should not be prevented from receiving her or his normal dialysis because he or she experienced another unrelated medical situation. Therefore, we proposed to allow payment for dialysis treatments for ESRD patients in the outpatient department of a hospital in specific situations. Payment would be limited to unscheduled dialysis for ESRD patients in exceptional circumstances. Outpatient dialysis for acute patients

would not be included in this payment mechanism.

In certain instances, it is appropriate to dialyze ESRD patients on an outpatient basis. We proposed to allow payment for these nonroutine dialysis treatments in medical situations in which the ESRD patient cannot obtain her or his regularly scheduled dialysis treatment at a certified ESRD facility. The circumstances in which we proposed to allow payment are limited to:

- Dialysis performed following or in connection with a vascular access procedure;
- Dialysis performed following treatment for an unrelated medical emergency; for example, if a patient goes to the emergency room for chest pains and misses a regularly scheduled dialysis treatment that cannot be rescheduled, we would allow the hospital to provide and bill Medicare for the dialysis treatment; and
- Emergency dialysis—Currently, the only mechanism available for payment in this situation is through an inpatient admission. We will maintain our policy that routine treatments in non-ESRD certified hospitals would not be payable under OPPS.

We believe it is important to make this change in the policy for two reasons:

- To ensure that hospital outpatient departments are paid for providing this much needed service; and
- To prevent dialysis patients from receiving interrupted care. Non-ESRD certified hospital outpatient facilities would bill Medicare using a new G code, G0GGG, ''Unscheduled or emergency treatment for dialysis for ESRD patient in the outpatient department of a hospital that does not have a certified ESRD facility.'' We proposed that this new code will have status indicator ''S'' and be assigned to APC 0170. Payment would be roughly equivalent to the reimbursement rate for acute dialysis. We proposed to implement this change effective January 1, 2003. Effective January 1, 2003, this would be the only way for non-ESRD certified hospital outpatient facilities to bill Medicare and be paid for providing nonroutine outpatient dialysis to ESRD patients.

We will be monitoring the use of this new code to ensure the following:

- Certified dialysis facilities are not incorrectly using this code.
- The same dialysis patient is not repeatedly using this code, which would indicate routine dialysis treatment.

When ESRD patients receive outpatient dialysis in non-ESRD certified hospital outpatient facilities, the patient's home facility would be responsible for obtaining and reviewing the patient's medical records to ensure that appropriate care was provided in the hospital and that modifications are made, if necessary, to the patient's plan of care upon her or his return to the facility. This ensures continuity of care for the patient.

We received eight comments on our proposal to allow payment for dialysis treatments for ESRD patients in the outpatient department of a hospital. Although all of the comments support our proposed changes, some commenters asked for clarification on issues pertaining to this provision.

Comment: One commenter requested that we provide clarification on how the payment rate would be determined for this service.

Response: In the August 9, 2002 proposed rule, we provided the payment rate for providing dialysis treatments for ESRD patients in the outpatient department of a hospital. The proposed rule stated that this service would be assigned Ambulatory Payment Classification (APC) 0170, and Addendum A provides the payment rate for this APC. Effective January 1, 2003, the payment national unadjusted rate for this service will be $252.16.

Comment: One commenter wanted clarification on how services typically associated with outpatient dialysis such as covered pharmaceuticals and laboratory testing will be accounted for under the proposed policy.

Response: We would pay separately for laboratory tests based on the laboratory fee schedule. Drugs may or may not be paid separately from the payment for the dialysis treatment. The drugs that would be paid separately would have a separate APC. If there is not a separate APC, then the drugs would be packaged into the APC paid for the dialysis treatment.

Comment: One commenter expressed concern that the proposal to require the ESRD patient's home facility to obtain and review the patient's medical records from the hospital would create an additional information collection burden for dialysis facilities. The commenter requested that we include language in the final rule that specifically outlines the hospital's responsibilities in providing the patient's medical records to the home facility.

Response: There should be a regular exchange of information between a patient's home facility and any treating facilities to verify the care that has been provided and to ensure that patients are not receiving inappropriate or incorrect treatment. The dialysis facility is, however, ultimately responsible for effectively coordinating the care of its patients, including the inclusion of all information in the patient's medical record, and we believe obtaining and reviewing information from other treating facilities is part of this responsibility. The medical record indicates what care has actually been provided, and it also provides the data for evaluation and documentation of the quality and appropriateness of the care delivered. We believe subsequent dialysis treatment at the patient's home facility should not be provided without information from another treatment facility because the home facility may need to make adjustments to the plan of care when the patient returns to the facility, so the facility should obtain this information from the hospital to implement any new strategies, etc. Furthermore, since dialysis facilities should already be collecting medical records for home dialysis patients and for traveling patients, we do not view this as an additional information collection burden. We view this as a responsibility within the facilities scope of practice.

Comment: One commenter cautioned us about the potential for abuse with this proposal and recommended that we develop clear guidelines governing the use of this new code.

Response: We agree with the commenter, and we plan to issue instructions for the use of the code as well as develop code edits to monitor the use of this code to prevent potential fraud and abuse. The instructions will be issued at a later date.

Comment: Another commenter requested clarification of the word ''routine,'' and what criteria that we will apply to establish whether a patient is receiving ''routine'' dialysis treatment. The commenter also requested documentation requirements (for example, diagnoses, other procedures, etc.) for meeting these ''exceptional circumstances'' defined in the August 9, 2002 proposed rule.

Response: We define ''routine'' dialysis as the three times per week maintenance treatment the same patient would normally receive at his or her home facility. We would consider a patient to be receiving routine dialysis if the claims received from the outpatient department indicated that the same patient received dialysis treatment more than once a week in this setting.

The August 9, 2002 proposed rule states that we would allow payment for this unscheduled dialysis under exceptional circumstances, and these circumstances would be (1) dialysis

performed following or in connection with a vascular access procedure; (2) dialysis performed following treatment for an unrelated medical emergency; and (3) emergency dialysis. These are the only situations in which payment would be made for dialysis provided in the outpatient department of a hospital without a certified dialysis facility. As stated above, we plan on issuing instructions governing the specific use of this code at a later date.

Comment: The commenter requested clarification as to whether an emergency department that is part of a larger hospital that contains a certified dialysis unit is already considered an ESRD certified location. Specifically, is this proposed payment change only for those providers that do not have a certified dialysis unit on their premises, making them a non-ESRD certified outpatient facility? If the answer is yes, then would the emergency department that is part of the hospital that has an ESRD-certified location bill the new dialysis G code if dialysis is given on an emergency basis while the ESRD certified location is closed?

Response: The proposed G code is specifically designated for an outpatient department of a hospital that does not have a certified ESRD facility. Therefore, a hospital's emergency department cannot use the code just because the certified dialysis facility is closed. The basis for this decision is to prevent potential fraud and abuse. We do not want dialysis facilities to use this as a means of circumventing the current requirements to receive a higher reimbursement rate for providing dialysis treatment. As stated above, we plan on issuing instructions governing the specific use of this code at a later date.

XI. Summary and Responses of Public Comments to CMS's Response to MedPAC Recommendations

In the August 9, 2002 proposed rule, we responded to the Medicare Payment Advisory Commission (MedPAC) March 2002 Report to the Congress: ''Medicare Payment Policy,'' recommendations relating to the OPPS (67 FR 52141 through 52143). We received no comments on our responses to MedPAC's recommendations. Therefore, we will not discuss that response further here. We did receive comments from MedPAC on other issues in the proposed rule. For convenience we group those comments and our responses here:

Comment: MedPAC endorsed our proposal to create APCs for procedures involving drug-eluting stents and noted, ''This step illustrates that CMS can respond rapidly to ensure adequate payment for technologies that are thought to be of a breakthrough nature.'' The Commission noted that our reliance on data from other countries to set the payment rate for this new technology appeared adequate in this instance. However, it expressed some reservation about the long-term issues that might attend more general use of such data. MedPAC has begun to consider these issues in more depth and urges us to do so as well.

Response: We appreciate the Commission's views. We have adopted our proposal for drug-eluting stents, including our method of setting the payment rate. We will give further consideration to the issues involved in use of foreign data.

Comment: MedPAC discussed the possibility that a pro rata reduction to payments for transitional pass-through drugs and devices would be needed this year, though we had not reached a conclusion on this question in the August 9, 2002 proposed rule. The Commission commented that even if a modest pro rata reduction is needed, it does not anticipate serious consequences for access to new technology services for several reasons. First, the methods for calculating transitional pass-through payments may overcompensate for these services. Second, hospitals are still likely to use these items to improve care and maintain reputations for excellence. Third, little evidence is available that indicates access problems resulting from the large pro rata reduction in 2002. Fourth, asking hospitals to share in the costs of new technologies gives them incentives to assess their value before adopting them.

Response: We have concluded that no pro rata reduction will be necessary for 2003. We appreciate and agree with the Commission's analysis of the possible effects of a pro rata reduction.

Comment: Regarding payment for medical devices no longer eligible for transitional pass-through payments, MedPAC urged us to work with stakeholders in instances where creditable evidence is available that coding issues may have led to inaccurate payment rates. The Commission does not believe that an extension of transitional pass-through eligibility is warranted or that data other than hospital cost data should be used where reliable hospital cost data are available. It also urged us to monitor beneficiary access to procedures that include such devices if payments are cut significantly.

Response: We agree that extension of transitional pass-through eligibility is not warranted, and we do not believe that the statute contemplates that it could be continued. We also agree that stakeholders may have valuable input, and as we describe elsewhere in this final rule, we have received a great deal of helpful information that has informed the policies adopted in this rule designed to moderate payment reductions that may be associated with use of devices (and of drugs) previously in transitional pass-through status. We also agree that monitoring access by beneficiaries to these procedures is important, and we expect to do so to the extent feasible.

Comment: MedPAC expressed concern that our proposal to pay separately for high-cost drugs but not for other drugs has the potential to distort the payment system. Where drugs may substitute for one another, hospitals may face incentives to use those paid separately. The Commission urged us to limit the amount of time this policy is followed and to work to move more drugs into the procedure APCs.

Response: We agree that this policy may have distorting effects on incentives, and we do not intend to use it longer than necessary. In future years, we hope to propose additional changes to this policy, and in particular to package drugs into procedure APCs where this approach appears reasonable. We hope further improvements in our data and further attention to the structure of APCs involving the use of drugs, such as those for infusion and injection, will provide the foundation for future policy development in this area.

Comment: MedPAC commented that hospital cost data are preferable to AWPs set by manufacturers. The Commission indicated the need to give careful consideration to stakeholder comments on payment for drugs and the importance of monitoring beneficiary access.

Response: We agree.

Comment: MedPAC commented that the reductions in payments for drugs that may no longer be eligible for transitional pass-through payments based on 95 percent of average wholesale price (AWP) will result in lower payments for these drugs than in other settings, such as physicians' offices. These differences may lead to shifts in the site of care based on financial considerations. MedPAC commented that this effect is not sufficient reason to change payments for these drugs in the hospital outpatient setting, but that it indicates the need for a new approach to paying for Part B drugs.

Response: The possibility of inappropriate shifts in site of service is a source of concern. We note, however, that payment rates for these drugs only shifted to 95 percent of AWP at the inception of the OPPS; before that time, Medicare paid for drugs in outpatient departments at reasonable cost, subject to statutory reductions. Medicare payment for drugs in physicians' offices has been set at 95 percent of AWP throughout this period. It is not clear that the increase in drug payments in outpatient departments from August 2000 to the present has led to substantial shifts in site of service, and the response to the forthcoming reductions may be muted as well. Nonetheless, we believe that Medicare should attempt to align payments across settings to the greatest extent possible in order to avoid inappropriate incentives to shift the site of service. In particular, we agree that a new approach to paying for Part B drugs would be desirable.

Comment: MedPAC noted that we have the statutory authority to modify updates to correct for unnecessary increases in the volume of services or for ''upcoding'' by hospitals. The Commission urged us to carefully track the volume of services and increases in coding intensity.

Response: We have not proposed any adjustment to the update for either of these reasons, and we will not adopt any such adjustment for 2003. We continue to monitor the progress of the OPPS system to discern whether we should make any such adjustment in the future.

Comment: MedPAC noted that small rural hospitals will continue to be held harmless for losses under the OPPS in 2003. The Commission urged us to study the performance of small rural hospitals and evaluate the impact of the end of their hold-harmless status.

Response: We agree that small rural hospitals warrant special attention. We expect to study the effect of the transitional corridor provision, including the protection it affords these hospitals, in the period since the implementation of the OPPS so that we can help evaluate what provision would be appropriate for 2004 and beyond.

XII. Provisions of the Final Rule With Comment for 2003

A. OPPS

The provisions of this final rule with comment restate changes to the Medicare hospital OPPS and CY 2003 payment rates including changes used to determine these payment rates set forth in the August 9, 2002 proposed rule, except as noted elsewhere in the preamble. The following is a highlight of provisions implemented in this final rule, which are discussed in detail above.

1. Statutory and Discretionary Changes

- We revised the methodology for calculating relative weights to dampen the difference in the median costs for all APCs for which the median costs fell more than 15 percent from 2002 to 2003; used only claims on which devices were reported to set the median for APCs for which the device was either essential or frequently used in the procedures in the APC; split some APCs for which devices were an issue to achieve more accurate pricing; limited the reduction in median costs for blood and certain blood products to 11 percent, which limited the reduction in payment from 2002 to 2003 to about 15 percent; used acquisition costs from external sources as a factor together with claims data in setting adjusted medians for four APCs.
- We reviewed and revised the composition of APCs to comply with the limitation on variation in procedure medians and to achieve more accurate reflections of the costs.
- We removed from pass-through status those drugs and devices that will have been on pass-through status for at least 2 years on January 1, 2003. We packaged the costs of the expiring devices into the payments for the APCs with which the devices were billed. We packaged the costs of the expiring drugs into the APCs with which the drugs were billed if the per encounter drug cost was less than $150; we established APCs for those drugs for which the per encounter drug cost was more than $150 and for blood and certain blood products. We paid for influenza and pneumococcal pneumonia vaccines and orphan drugs on a reasonable cost basis.
- We estimated the amount of payment that would be made under the pass through provisions and compared it to 2.5 percent of the projected program expenditures; we determined that no pro rata reduction would be needed for 2003, and we adjusted the conversion factor accordingly.
- We established the percentages by which pass-through devices would be reduced to remove the part of the payment that is packaged into the APC when it is billed with the device.
- We finalized the regulations that describe the criteria that must be met for a device to get a pass-through code.
- We issued the 2003 wage index and conversion factor that would be applied to the relative weights to determine the amount of payment for a particular hospital.

2. Changes to the Regulations Text

- We amended § 419.21(d)(3) to delete influenza and pneumococcal pneumonia vaccines from the list of items that are paid to CORFs, HHAs, and hospices under OPPS.
- We amended § 419.66(c)(1) to specify that we must establish a new category for a medical device if it is not described by any category previously in effect as well as an existing category. We received no comments concerning this technical correction to our regulations text. We are making this proposal final in this final rule.

B. Payment Suspension for Unfiled Cost Reports

We are adopting the provisions set forth in the proposed rule without change.

C. Partial Hospitalization Services

In the August 9, 2002 proposed rule, we indicated we would be addressing comments received on our proposal to establish a new payment amount for partial hospitalization services and remove clinical social worker services from the partial hospitalization benefit. Upon further review we have determined that we will not include this issue in this final rule, but will address it in future rulemaking.

D. Pneumococcal and Influenza Vaccines

Section 419.21(d)(3) states that ''Pneumococcal vaccine, influenza vaccine, and hepatitis B vaccine'' are paid under the OPPS for comprehensive outpatient rehabilitation facilities, home health agencies, and hospices. There is no specific inclusion of hospitals, but we have paid hospitals for them under the OPPS since the OPPS began. We are removing the pneumococcal vaccine and influenza vaccine from this paragraph and want to pay for it under reasonable cost. We are requesting public comment on this change.

XIII. Response to Public Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to comments in the preamble to that document.

XIV. Collection of Information Requirements

This rule does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

XV. Regulatory Impact Analysis

The regulatory impact analysis for this final rule consists of an impact analysis for the OPPS provisions and a regulatory impact statement for the provision for payment suspension for unfiled cost reports.

A. OPPS

1. General

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We estimate the effects of the provisions that will be implemented by this final rule will result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from changes in the final rule as well as enrollment, utilization, and case mix changes) in expenditures under the OPPS for CY 2003 compared to CY 2002 to be approximately $1.372 billion. Therefore, this final rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year (see 65 FR 69432).

For purposes of the RFA, we have determined that approximately 37 percent of hospitals will be considered small entities according to the Small Business Administration (SBA) size standards. We do not have data available to calculate the percentages of entities in the pharmaceutical preparation manufacturing, biological products, or medical instrument industries that would be considered to be small entities according to the SBA size standards. For the pharmaceutical preparation manufacturing industry (NAICS 325412), the size standard is 750 or fewer employees and $67.6 billion in annual sales (1997 business census). For biological products (except diagnostic) (NAICS 325414), with $5.7 billion in annual sales, and medical instruments (NAICS 339112), with $18.5 billion in annual sales, the standard is 50 or fewer employees (see the standards Web site at *http://www.sba.gov/regulations/siccodes/*). Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds (or New England County Metropolitan Area (NECMA)). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the OPPS, we classify these hospitals as urban hospitals. We believe that the changes in this final rule will affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Therefore, we conclude that this final rule has a significant impact on a substantial number of small entities. However, the statute provides for small rural hospitals (of fewer than 100 beds) to be held harmless by the law and to continue to be paid at cost; therefore this final rule has no impact on them.

Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule will not mandate any requirements for State, local, or tribal governments. This final rule imposes no unfunded mandates on the private sector.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this final rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have an impact on the rights, roles, and responsibilities of State, local or tribal governments. The impact analysis (see Table 10) shows that payments to governmental hospitals (including State, local, and tribal governmental hospitals) will increase by 5 percent under the final rule.

2. Changes in this Final Rule

We are making several changes to the OPPS that are required by the statute. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We are also required under section 1833(t)(9)(A) of the Act to revise, not less often than annually, the wage index and other adjustments. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, in this final rule, we are updating the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2003 as we discuss in sections VIII and VI, respectively, of this preamble. We are also revising the relative APC payment weights based on claims data from January 1, 2001 through December 31, 2001. Finally, we are removing 95 devices and more than 200 drugs and biologicals from pass-through payment status.

Under this final rule, the change to the conversion factor as provided by statute will increase total OPPS payments by 3.7 percent in 2003. The changes to the wage index and to the APC weights (which incorporate the cessation of pass-through payments for many drugs and devices) do not increase OPPS payments because the OPPS is budget neutral. However, the

wage index and APC weight changes do change the distribution of payments within the budget neutral system as shown in Table 10 and described in more detail in this section.

Alternatives Considered

Alternatives to the changes we are making and the reasons that we are choosing not to make them are discussed throughout this final rule. Below we discuss options we considered when analyzing methodologies to appropriately recognize the costs of former pass-through items. For a more detailed discussion, see section IV.C regarding the expiration of pass-through payment for devices and section IV.D regarding the expiration of pass-through payment for drugs and biologicals.

Payment for Categories of Devices

We considered establishing separate APCs for categories of devices and paying for them separately. We are not choosing this option because we believe that to the extent possible, hospital payment for procedures and visits should include all of the costs required to provide the procedures and visits.

A second option we considered involved (1) packaging some categories of devices into the procedures with which they were billed in 2001 and (2) paying the rest through separate APCs (as discussed in section IV of this final rule.). We are not choosing this option because we believe that devices are routinely used in the services for which they are needed and therefore are consistently paid at the cost of providing the service. Furthermore, criteria that will provide a basis for some devices to be packaged and for others to be paid separately must be developed and approved, thereby further complicating an already complex payment system.

Payment for Drugs and Biologicals

We considered continuing to make separate payment for all drugs and biologicals through separate APCs. We are not choosing to pay separately for all drugs through separate APCs because we believe that, to the extent possible, hospital payment for services should include all of the costs of the services. We believe that drugs should be packaged with the services in which they are furnished except when we determine that there is a valid reason to do otherwise. However, we recognize that (unlike the stability that exists with device usage with the applicable procedures) the use of drugs may vary widely depending upon patient and disease characteristics. Therefore, packaging payment for all drugs may, in some cases, provide inadequate payment for the services furnished. Where a hospital has a disproportionate share of patients who need greater amounts of expensive drugs, underpayment for the drugs needed by these patients could result in cessation of needed services. For the first year that we are ceasing transitional pass-through payment for drugs, we decided to proceed cautiously by paying separately for drugs when the cost per encounter was more than $150 or when special characteristics existed (for example, orphan drugs, blood products).

We also considered packaging the costs of all drugs into the cost of the associated procedures with which they were billed in 2001. We did not package all payment for drugs into the payment for the procedures because, while this packaging is ultimately our goal, we believe, for the reasons indicated above, that we need to proceed cautiously to ensure that we do not inadvertently threaten access to needed care.

Conclusion

It is clear that the changes in this final rule will affect both a substantial number of rural hospitals as well as other classes of hospitals, and the effects on some may be significant. Therefore, the discussion below, in combination with the rest of this final rule, constitutes a regulatory impact analysis.

The OPPS rates for CY 2003 will have, overall, a positive effect for every category of hospital with the exception of children's hospitals, which are held harmless under the OPPS. These changes in the OPPS for 2003 will result in an overall 3.7 percent increase in Medicare payments to hospitals, exclusive of outlier and transitional pass-through payments and transitional corridor payments. As described in the preamble, budget neutrality adjustments are made to the conversion factor and the weights to ensure that the revisions in the wage index, APC groups, and relative weights do not affect aggregate payments. The impact of the wage and recalibration changes does vary somewhat by hospital group. Estimates of these impacts are displayed on Table 10.

The overall projected increase in payments for urban hospitals is slightly lower (3.1 percent) than the average increase for all hospitals (3.7 percent) while the increase for rural hospitals is significantly greater (6.2 percent) than the average increase. Rural hospitals gain 2.2 percent from the wage index change, and also gain 0.1 percent from APC changes. A discussion of the distribution of outlier payments that we project under this final rule can be found under section XV.A.4 below. Table 11 presents the outlier distribution that we expect to see under this final rule.

3. Limitations of Our Analysis

The distributional impacts represent the projected effects of the policy changes, as well as statutory changes effective for 2003, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per service while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service mix, or number of encounters.

4. Estimated Impacts of This Final Rule on Hospitals

The OPPS is a budget neutral payment system under which the increase to the total payments made under OPPS is limited by the increase to the conversion factor set under the methodology in the statute. The impact tables show the redistributive effects of the wage index and APC changes. In some cases, under this final rule, hospitals will receive more total payment than in 2002 while in other cases they will receive less total payment than they received in 2002. The impact of this final rule will depend on a number of factors, most significant of which are the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change) and the impact of the wage index changes on the hospital.

Column 4 in Table 12 represents the full impact on each hospital group of all the changes for 2003. Columns 2 and 3 in the table reflect the independent effects of the change in the wage index and the APC reclassification and recalibration changes, respectively. We excluded critical access hospitals (CAHs) from the analysis of the impact of the 2003 OPPS rates that is summarized in Table 12. For that reason, the total number of hospitals included in Table 10 (4,551) is lower than in previous years. CAHs are excluded from the OPPS.

In general, the wage index changes favor rural hospitals, particularly the largest in bed size and volume. The only rural hospitals that will experience a negative impact due to wage index changes are those in Puerto Rico, a decrease of 3.2 percent. Conversely, the urban hospitals are generally negatively

affected by wage index changes, with the largest decreases occurring in those with 300 to 499 beds (−0.7 percent) and those in the Middle Atlantic (−1.0 percent), Pacific (−1.2 percent), and Puerto Rico Regions (−1.6 percent). However, this effect is somewhat lessened by the distribution of outlier payments as discussed in more detail below.

The APC reclassification and recalibration changes also favor rural hospitals and have a negative effect on urban hospitals in excess of 200 beds. Specifically, urban hospitals with 300 to 499 beds (−0.6 percent decrease) and urban hospitals in excess of 500 beds (a −0.8 percent decrease) all show a decrease attributed to APC recalibration. However, this decrease is much less than what would have occurred under the proposed rule.

In urban areas, hospitals that provide a lower volume of outpatient services are projected to receive a larger increase in payments than higher volume hospitals. In rural areas, hospitals with higher volumes are expected to receive higher increases in payments. In rural areas, hospitals with volumes greater than 42,999 services are projected to experience a significant increase in payments (7.7 percent). The less favorable impact for the high volume urban hospitals is attributable to both wage index and APC changes. For example, urban hospitals providing more than 42,999 services are projected to gain a combined 2.8 percent due to these changes.

Major teaching hospitals are projected to experience a smaller increase in payments (2.7 percent) than the aggregate for all hospitals (3.7 percent) due to negative impacts of the wage index (−0.3 percent) and recalibration (−0.8 percent). Hospitals with less intensive teaching programs are projected to experience an overall increase (3.2 percent) that is smaller than the average for all hospitals.

TABLE 12.—IMPACT OF CHANGES FOR CY 2003 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

[Percent change in total payments to hospitals (program and beneficiary); does not include hold harmless, corridor, outlier or transitional pass-through payments]

	Number of Hospitals[1] (1)	New Wage Index[2] (2)	APC Changes[3] (3)	All CY 2003 Changes[4] (4)
ALL HOSPITALS	4,519	0	0	3.7
NON-TEFRA HOSPITALS	3,989	0	−0.1	3.6
URBAN HOSPS	2,420	−0.5	−0.1	3.1
LARGE URBAN (GT 1 MILL.)	1,397	−0.6	−0.1	3.1
OTHER URBAN (LE 1 MILL.)	1,023	−0.5	−0.1	3.1
RURAL HOSPS	1,569	2.2	0.1	6.2
BEDS (URBAN):				
0–99 BEDS	550	−0.4	0.7	4.0
100–199 BEDS	877	−0.6	0.6	3.7
200–299 BEDS	488	−0.6	0.1	3.3
300–499 BEDS	364	−0.7	−0.6	2.4
500+ BEDS	141	−0.1	−0.8	2.8
BEDS (RURAL):				
0–49 BEDS	752	0.2	0	4.0
50–99 BEDS	478	1.4	−0.3	4.9
100–149 BEDS	200	2.4	0.3	6.6
150–199 BEDS	73	5.4	−0.5	8.9
200+ BEDS	66	3.1	0.8	8.0
VOLUME (URBAN):				
LT 5,000	182	0.9	3.4	8.0
5,000–10,999	293	−0.8	2.2	5.2
11,000–20,999	476	−0.7	1.1	4.2
21,000–42,999	667	−0.7	0.2	3.2
GT 42,999	802	−0.5	−0.4	2.8
VOLUME (RURAL):				
LT 5,000	334	0	1.1	4.9
5,000–10,999	419	0.3	1.2	5.4
11,000–20,999	387	1.2	0	5.0
21,000–42,999	295	1.9	0	5.8
GT 42,999	134	4.1	−0.3	7.7
REGION (URBAN):				
NEW ENGLAND	127	−0.6	0.4	3.4
MIDDLE ATLANTIC	372	−1	0.1	2.7
SOUTH ATLANTIC	367	−0.3	0.5	3.9
EAST NORTH CENT.	411	−0.7	−0.9	2.1
EAST SOUTH CENT.	153	−0.8	−0.1	2.8
WEST NORTH CENT.	170	−0.6	−1.1	2.0
WEST SOUTH CENT.	292	1	0	4.8
MOUNTAIN	122	0.2	−0.8	3.0
PACIFIC	367	−1.2	0.8	3.3
PUERTO RICO	39	−1.6	2.1	4.1
REGION (RURAL):				
NEW ENGLAND	40	1.7	−0.2	5.3
MIDDLE ATLANTIC	63	1.9	−0.5	5.3
SOUTH ATLANTIC	224	2.4	0.9	7.2
EAST NORTH CENT.	212	1.1	−1.7	3.2
EAST SOUTH CENT.	232	2.2	1.2	7.3
WEST NORTH CENT.	271	1.8	−0.6	5.0

TABLE 12.—IMPACT OF CHANGES FOR CY 2003 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

[Percent change in total payments to hospitals (program and beneficiary); does not include hold harmless, corridor, outlier or transitional pass-through payments]

	Number of Hospitals[1] (1)	New Wage Index[2] (2)	APC Changes[3] (3)	All CY 2003 Changes[4] (4)
WEST SOUTH CENT.	278	1.9	1.4	7.2
MOUNTAIN	141	4.6	−0.6	7.9
PACIFIC	103	4.9	1	10.0
PUERTO RICO	5	−3.2	7.2	7.6
TEACHING STATUS:				
NON-TEACHING	2,922	0.3	0.3	4.4
MINOR	782	−0.3	−0.2	3.2
MAJOR	284	−0.3	−0.8	2.7
DSH PATIENT PERCENT:				
0	11	5.3	5.5	15.3
GT 0–0.10	975	−0.2	−0.6	2.9
0.10–0.16	872	0.6	−0.6	3.7
0.16–0.23	766	−0.6	0	3.1
0.23–0.35	755	−0.1	0.4	4.1
GE 0.35	610	0.1	1.6	5.5
URBAN IME/DSH:				
IME & DSH	982	−0.6	−0.4	2.7
IME/NO DSH	0	0	0	0.0
NO IME/DSH	1,432	−0.5	0.4	3.6
NO IME/NO DSH	6	6.1	5.1	15.7
RURAL HOSP. TYPES:				
NO SPECIAL STATUS	607	0.5	0.3	4.6
RRC	167	4.2	0.2	8.4
SCH/EACH	507	1.4	−0.1	5.1
MDH	199	0.5	−0.7	3.6
SCH AND RRC	75	3.8	0.1	7.9
TYPE OF OWNERSHIP:				
VOLUNTARY	2,434	−0.1	−0.2	3.5
PROPRIETARY	703	−0.5	0.5	3.7
GOVERNMENT	852	0.6	0	4.4
SPECIALTY HOSPITALS:				
EYE AND EAR	13	−1.3	9.1	11.7
TRAUMA	153	−0.3	−0.6	2.9
CANCER	10	1	−4.5	0.4
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES):				
REHAB	163	10.1	0.8	14.7
PSYCH	191	0	7.4	11.4
LTC	135	4.3	15.1	23.0
CHILDREN	41	−1.4	−1	1.3

[1] Some data necessary to classify hospitals by category were missing; thus, the total number of hospitals in each category may not equal the national total.

[2] This column shows the impact of updating the wage index used to calculate payment by applying the FY 2003 hospital inpatient wage index after geographic reclassification by the Medicare Geographic Classification Review Board. The hospital inpatient final rule for FY 2003 was published in the **Federal Register** on May 9, 2002.

[3] This column shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the recalibration of APC weights based on 2001 hospital claims data.

[4] This column shows changes in total payment from CY 2002 to CY 2003, excluding outlier and pass-through payments. It incorporates all of the changes reflected in columns 2 and 3. In addition, it shows the impact of the FY 2003 payment update. The sum of the columns may be different from the percentage changes shown here due to rounding.

Note: For CY 2003, under the OPPS transitional corridor policy, the following categories of hospitals are held harmless compared to their 1996 payment margin for these services: cancer and children's hospitals and rural hospitals with 100 or fewer beds.

As stated elsewhere in this preamble, we have allocated 2 percent of the estimated 2003 expenditures to outlier payments. In Table 13 below, we provide a distribution by percentage of the total projected outlier payments for the categories of hospitals that we show in the impact table (Table 10).

We project, based on the mix of services for the hospitals that will be paid under the OPPS in 2003, that most hospitals will receive outlier payments.

The anticipated outlier payments for urban hospitals can be expected to ameliorate the impact of the wage index and APC changes on payments to urban hospitals.

TABLE 13.—DISTRIBUTION OF OUTLIER PAYMENTS FOR CY 2003 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of Hospitals	Percent of Total Hospitals	Number of Hospitals with Outliers	Percent of Total Outlier Payments
ALL HOSPITALS	4,519	100.00	4,298	100.00
NON-TEFRA HOSPITALS	3,989	88.20	3,977	99.40
URBAN HOSPS	2,420	53.60	2,413	83.20
LARGE URBAN (GT 1 MILL.)	1,397	31.00	1,394	56.00
OTHER URBAN (LE 1 MILL.)	1,023	22.60	1,019	27.20
RURAL HOSPS	1,569	34.80	1,564	16.20
BEDS (URBAN):				
0–99 BEDS	550	12.20	545	7.20
100–199 BEDS	877	19.40	875	18.20
200–299 BEDS	488	10.80	488	16.80
300–499 BEDS	364	8.00	364	21.00
500 + BEDS	141	3.20	141	19.80
BEDS (RURAL):				
0–49 BEDS	752	16.60	749	4.40
50–99 BEDS	478	10.60	477	5.00
100–149 BEDS	200	4.40	199	2.40
150–199 BEDS	73	1.60	73	2.00
200 + BEDS	66	1.40	66	2.20
VOLUME (URBAN):				
LT 5,000	182	4.00	176	1.00
5,000–10,999	293	6.40	292	2.80
11,000–20,999	476	10.60	476	6.80
21,000–42,999	667	14.80	667	17.60
GT 42,999	802	17.80	802	55.00
VOLUME (RURAL):				
LT 5,000	334	7.40	330	1.00
5,000–10,999	419	9.20	418	2.40
11,000–20,999	387	8.60	387	4.00
21,000–42,999	295	6.60	295	4.20
GT 42,999	134	3.00	134	4.40
REGION (URBAN):				
NEW ENGLAND	127	2.80	126	5.60
MIDDLE ATLANTIC	372	8.20	371	24.20
SOUTH ATLANTIC	367	8.20	366	11.40
EAST NORTH CENT	411	9.00	408	14.80
EAST SOUTH CENT	153	3.40	153	3.20
WEST NORTH CENT	170	3.80	170	4.20
WEST SOUTH CENT	292	6.40	292	8.00
MOUNTAIN	122	2.60	122	3.00
PACIFIC	367	8.20	366	8.80
PUERTO RICO	39	0.80	39	0.00
REGION (RURAL):				
NEW ENGLAND	40	0.80	40	1.00
MIDDLE ATLANTIC	63	1.40	63	1.00
SOUTH ATLANTIC	224	5.00	222	3.00
EAST NORTH CENT	212	4.60	211	3.00
EAST SOUTH CENT	232	5.20	232	1.60
WEST NORTH CENT	271	6.00	270	2.40
WEST SOUTH CENT	278	6.20	278	1.60
MOUNTAIN	141	3.20	141	1.40
PACIFIC	103	2.20	102	1.20
PUERTO RICO	5	0.20	5	0.00
TEACHING STATUS:				
NON-TEACHING	2,922	64.60	2,910	40.40
MINOR	782	17.40	782	27.00
MAJOR	284	6.20	284	31.80
DSH PATIENT PERCENT:				
0	11	0.20	11	0.00
GT 0–0.10	975	21.60	973	24.60
0.10–0.16	872	19.20	872	19.20
0.16–0.23	766	17.00	764	17.60
0.23–0.35	755	16.80	752	19.40
GE 0.35	610	13.40	605	18.40
URBAN IME/DSH:				
IME & DSH	982	21.80	982	56.60
IME/NO DSH	0	0.00	0	0.00
NO IME/DSH	1,432	31.60	1,425	26.40
NO IME/NO DSH	6	0.20	6	0.00
RURAL HOSP. TYPES:				
NO SPECIAL STATUS	607	13.40	605	5.00

TABLE 13.—DISTRIBUTION OF OUTLIER PAYMENTS FOR CY 2003 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of Hospitals	Percent of Total Hospitals	Number of Hospitals with Outliers	Percent of Total Outlier Payments
RRC	167	3.60	166	4.00
SCH/EACH	507	11.20	507	4.40
MDH	199	4.40	198	1.20
SCH AND RRC	75	1.60	75	1.60
TYPE OF OWNERSHIP:				
VOLUNTARY	2,434	53.80	2,431	73.60
PROPRIETARY	703	15.60	699	10.60
GOVERNMENT	852	18.80	847	15.20
SPECIALTY HOSPITALS:				
EYE AND EAR	13	0.20	13	0.20
TRAUMA	153	3.40	153	15.00
CANCER	10	0.20	10	3.60
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES):				
REHAB	163	3.60	115	0.20
PSYCH	191	4.20	67	0.00
LTC	135	3.00	99	0.20
CHILDREN	41	1.00	40	0.20

5. Estimated Impacts of This Final Rule on Beneficiaries

For services for which the beneficiary pays a coinsurance of 20 percent of the payment rate, the beneficiary share of payment will increase for services for which OPPS payments will rise and will decrease for services for which OPPS payments will fall. For example for a mid level office visit (APC 0601), the minimum unadjusted copayment in 2002 was $9.67; under this final rule, the minimum unadjusted copayment for APC 601 is $10.11 because the OPPS payment for the service will increase under this final rule. For some services (those services for which a national unadjusted copayment amount is shown in Addendum B), however, the beneficiary copayment is frozen based on historic data and will not change, therefore not presenting any potential impact on beneficiaries.

However, in all cases, the statute limits beneficiary liability for copayment for a service to the inpatient hospital deductible for the applicable year. This amount was $812 for 2002, and is $840 for 2003. In general, the impact of this final rule on beneficiaries will vary based on the service the beneficiary receives and whether the copayment for the service is one that is frozen under the OPPS.

B. Payment Suspension for Unfiled Cost Reports

Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Public Law 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. (A description of each of these requirements is stated above in section XV.A.1.)

We have determined that the payment suspension provision does not have an economic impact on Medicare payments or other payments to providers. We are allowing the Secretary flexibility in payment suspensions, but we are not altering the final payment determination in any way. With the implementation of the various prospective payment systems, the majority of the payment to providers is based on the PPS methodology and not on the cost report. Suspending all payments because the cost report is not timely filed negatively affects providers. Providing the Secretary with flexibility in payment suspension can lessen the financial impact on providers. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. Under the requirement for Unfunded Mandates, this final rule will not have an economic effect on State, local, or tribal governments, in the aggregate, or on the private sector.

Anticipated Effects

1. Effects on Providers That File Cost Reports

The majority of providers that file cost reports comply with the timeliness provisions and will be unaffected by this regulation. In FY 2000, collectively 16 percent of hospitals, skilled nursing facilities, and home health agencies filed late cost reports. Of this 16 percent, 65 percent of those were only 1 day late. Currently, when a provider fails to file an acceptable cost report, the provider is placed on a complete payment suspension. Under this provision, for those providers who do not file timely, an immediate payment suspension less than the total suspension currently required might be imposed if the Secretary deemed it appropriate, which will allow the provider to more easily continue operations while completing and submitting the acceptable cost report.

2. Effects on Other Providers

The payment suspension provision does not affect other providers.

3. Effects on the Medicare Program

The provision will allow the Secretary to more effectively manage the Medicare program by imposing other than complete payment suspension when it is appropriate to do so. The Medicare program benefits because immediate complete payment suspension can be disruptive to providers and may negatively affect the care of Medicare patients. There are no costs to the Medicare program to doing so, because when the cost report is submitted, the suspended payments are returned to the provider.

4. Effects on Beneficiaries

We have determined that this provision has a potentially positive impact on beneficiaries. Under this provision, the Secretary will have the

discretion to impose less than 100 percent payment suspension when a provider fails to timely file an acceptable cost report. Doing so will lessen the financial burden on the provider and thereby allow it to provide adequate services to its patient population as it works to complete and file an acceptable cost report.

Alternatives Considered

We considered not revising existing § 405.371(c) to provide that payment suspension could be ''in whole or in part.'' However, we did not choose this option because we believe the Secretary should have the discretion to impose partial payment suspensions when circumstances warrant in order to more effectively manage the Medicare program.

Conclusion

In conclusion, we have determined that the payment suspension provision does not have an economic impact on Medicare payments.

C. Federalism

Since this regulation does not impose any costs on State or local governments, it will not have an effect on State or local governments. State or local governments will have no roles or responsibilities associated with this provision.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

1. The authority citation for subpart C of part 405 continues to read as follows:

Authority: Secs. 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

2. Section 405.371(c) is revised to read as follows:

§ 405.371 Suspension, offset and recoupment of Medicare payments to providers and suppliers of services.

* * * * *

(c) Suspension of payment in the case of unfiled cost reports. If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the intermediary to be acceptable. In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

1. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

2. In § 419.21, paragraph (d)(3) is revised to read as follows:

§ 419.21 Hospital outpatient services subject to the outpatient prospective payment system.

* * * * *

(d) * * *

(3) Hepatitis B vaccine.

§ 419.66 [Amended]

3. In § 419.66, paragraph (c)(1) is amended by adding the phrase ''or by any category previously in effect'' after ''categories'' and before ''and''.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary (Medical Insurance Program).

Dated: October 23, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare and Medicaid Services.

Approved: October 23, 2002.

Tommy G. Thompson,

Secretary.

ADDENDUM A.—LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCS) WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS

[Calendar Year 2003]

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted copayment	Minimum unadjusted copayment
0001	Level I Photochemotherapy	S	0.3779	$19.71	$7.09	$3.94
0002	Fine needle Biopsy/Aspiration	T	0.5911	$30.83	.....	$6.17
0003	Bone Marrow Biopsy/Aspiration	T	1.2306	$64.18	.....	$12.84
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow	T	1.7441	$90.96	$23.47	$18.19
0005	Level II Needle Biopsy /Aspiration Except Bone Marrow	T	3.1201	$162.72	$71.59	$32.54
0006	Level I Incision & Drainage	T	1.7926	$93.49	$24.12	$18.70
0007	Level II Incision & Drainage	T	10.0191	$522.51	$108.89	$104.50
0008	Level III Incision and Drainage	T	16.1430	$841.87	.....	$168.37
0009	Nail Procedures	T	0.6298	$32.84	$8.34	$6.57
0010	Level I Destruction of Lesion	T	0.6589	$34.36	$10.08	$6.87
0011	Level II Destruction of Lesion	T	1.8507	$96.52	$27.88	$19.30
0012	Level I Debridement & Destruction	T	0.7849	$40.93	$11.18	$8.19
0013	Level II Debridement & Destruction	T	1.0756	$56.09	$14.20	$11.22
0015	Level III Debridement & Destruction	T	1.5407	$80.35	$20.35	$16.07
0016	Level IV Debridement & Destruction	T	2.6162	$136.44	$57.31	$27.29
0017	Level VI Debridement & Destruction	T	15.8233	$825.20	$227.84	$165.04
0018	Biopsy of Skin/Puncture of Lesion	T	0.9399	$49.02	$16.04	$9.80
0019	Level I Excision/ Biopsy	T	3.7693	$196.57	$71.87	$39.31
0020	Level II Excision/ Biopsy	T	7.1898	$374.96	$113.25	$74.99
0021	Level III Excision/ Biopsy	T	13.9338	$726.66	$219.48	$145.33
0022	Level IV Excision/ Biopsy	T	17.3930	$907.06	$354.45	$181.41
0023	Exploration Penetrating Wound	T	2.5193	$131.38	$40.37	$26.28
0024	Level I Skin Repair	T	1.8507	$96.52	$34.75	$19.30
0025	Level II Skin Repair	T	5.8623	$305.72	$115.49	$61.14
0027	Level IV Skin Repair	T	15.2225	$793.87	$329.72	$158.77
0028	Level I Breast Surgery	T	16.8698	$879.78	$303.74	$175.96
0029	Level II Breast Surgery	T	28.7881	$1,501.33	$632.64	$300.27
0030	Level III Breast Surgery	T	37.5185	$1,956.63	$763.55	$391.33
0032	Insertion of Central Venous/Arterial Catheter	T	11.4726	$598.31	.....	$119.66
0033	Partial Hospitalization	P	4.6026	$240.03	$48.17	$48.01
0035	Placement of Arterial or Central Venous Catheter	T	0.2229	$11.62	$3.51	$2.32
0041	Level I Arthroscopy	T	26.1234	$1,362.36	.....	$272.47
0042	Level II Arthroscopy	T	40.9680	$2,136.52	$804.74	$427.30
0043	Closed Treatment Fracture Finger/Toe/Trunk	T	2.4999	$130.37	.....	$26.07
0045	Bone/Joint Manipulation Under Anesthesia	T	12.9357	$674.61	$268.47	$134.92
0046	Open/Percutaneous Treatment Fracture or Dislocation	T	29.2920	$1,527.61	$535.76	$305.52
0047	Arthroplasty without Prosthesis	T	28.2842	$1,475.05	$537.03	$295.01
0048	Arthroplasty with Prosthesis	T	40.6289	$2,118.84	$695.60	$423.77
0049	Level I Musculoskeletal Procedures Except Hand and Foot	T	18.6042	$970.23	$197.14	$194.05
0050	Level II Musculoskeletal Procedures Except Hand and Foot	T	23.3037	$1,215.31	.....	$243.06
0051	Level III Musculoskeletal Procedures Except Hand and Foot	T	32.9062	$1,716.09	.....	$343.22
0052	Level IV Musculoskeletal Procedures Except Hand and Foot	T	40.7646	$2,125.91	.....	$425.18
0053	Level I Hand Musculoskeletal Procedures	T	14.1760	$739.29	$253.49	$147.86
0054	Level II Hand Musculoskeletal Procedures	T	22.7223	$1,184.99	.....	$237.00
0055	Level I Foot Musculoskeletal Procedures	T	17.6740	$921.72	$355.34	$184.34
0056	Level II Foot Musculoskeletal Procedures	T	22.1700	$1,156.19	$405.81	$231.24
0057	Bunion Procedures	T	22.9064	$1,194.59	$475.91	$238.92
0058	Level I Strapping and Cast Application	S	1.0368	$54.07	.....	$10.81
0060	Manipulation Therapy	S	0.3294	$17.18	.....	$3.44
0068	CPAP Initiation	S	2.0736	$108.14	$59.48	$21.63
0069	Thoracoscopy	T	27.5575	$1,437.15	$591.64	$287.43
0070	Thoracentesis/Lavage Procedures	T	3.3623	$175.35	.....	$35.07
0071	Level I Endoscopy Upper Airway	T	0.9205	$48.00	$12.89	$9.60
0072	Level II Endoscopy Upper Airway	T	1.1628	$60.64	$26.68	$12.13
0073	Level III Endoscopy Upper Airway	T	3.1976	$166.76	$73.38	$33.35
0074	Level IV Endoscopy Upper Airway	T	12.8582	$670.57	$295.70	$134.11
0075	Level V Endoscopy Upper Airway	T	19.6604	$1,025.31	$445.92	$205.06
0076	Endoscopy Lower Airway	T	8.9533	$466.92	$189.82	$93.38
0077	Level I Pulmonary Treatment	S	0.2907	$15.16	$8.34	$3.03
0078	Level II Pulmonary Treatment	S	0.6492	$33.86	$14.55	$6.77
0079	Ventilation Initiation and Management	S	1.6376	$85.40	.....	$17.08
0080	Diagnostic Cardiac Catheterization	T	35.2996	$1,840.91	$838.92	$368.18
0081	Non-Coronary Angioplasty or Atherectomy	T	43.5067	$2,268.92	.....	$453.78
0082	Coronary Atherectomy	T	86.4321	$4,507.52	$1,293.59	$901.50
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	T	51.9755	$2,710.57	.....	$542.11
0084	Level I Electrophysiologic Evaluation	S	9.3312	$486.63	.....	$97.33
0085	Level II Electrophysiologic Evaluation	T	41.7238	$2,175.94	$480.03	$435.19
0086	Ablate Heart Dysrhythm Focus	T	52.8282	$2,755.04	$936.35	$551.01

ADDENDUM A.—LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCS) WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS—Continued

[Calendar Year 2003]

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted copayment	Minimum unadjusted copayment
0087	Cardiac Electrophysiologic Recording/Mapping	T	39.3983	$2,054.66	.....	$410.93
0088	Thrombectomy	T	32.5768	$1,698.91	$655.22	$339.78
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	T	112.5555	$5,869.88	$1,722.59	$1,173.98
0090	Insertion/Replacement of Pacemaker Pulse Generator	T	87.9631	$4,587.36	$1,651.45	$917.47
0091	Level II Vascular Ligation	T	26.7048	$1,392.68	$348.23	$278.54
0092	Level I Vascular Ligation	T	23.7882	$1,240.58	$505.37	$248.12
0093	Vascular Reconstruction/Fistula Repair without Device	T	20.6294	$1,075.84	$277.34	$215.17
0094	Level I Resuscitation and Cardioversion	S	3.8371	$200.11	$67.63	$40.02
0095	Cardiac Rehabilitation	S	0.6105	$31.84	$16.73	$6.37
0096	Non-Invasive Vascular Studies	S	1.7054	$88.94	$48.15	$17.79
0097	Cardiac and Ambulatory Blood Pressure Monitoring	X	1.0077	$52.55	$23.80	$10.51
0098	Injection of Sclerosing Solution	T	1.6666	$86.91	$20.88	$17.38
0099	Electrocardiograms	S	0.3682	$19.20	.....	$3.84
0100	Cardiac Stress Tests	X	1.6085	$83.88	$41.44	$16.78
0101	Tilt Table Evaluation	S	4.2247	$220.32	$105.27	$44.06
0103	Miscellaneous Vascular Procedures	T	11.8408	$617.51	$223.63	$123.50
0104	Transcatheter Placement of Intracoronary Stents	T	76.5486	$3,992.09	.....	$798.42
0105	Revision/Removal of Pacemakers, AICD, or Vascular	T	18.5945	$969.72	$370.40	$193.94
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T	54.8243	$2,859.14	.....	$571.83
0107	Insertion of Cardioverter-Defibrillator	T	326.2231	$17,012.86	$3,699.14	$3,402.57
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T	443.5460	$23,131.37	.....	$4,626.27
0109	Removal of Implanted Devices	T	7.4708	$389.61	$131.49	$77.92
0110	Transfusion	S	4.0309	$210.22	.....	$42.04
0111	Blood Product Exchange	S	14.9803	$781.24	$217.61	$156.25
0112	Apheresis, Photopheresis, and Plasmapheresis	S	36.4236	$1,899.53	$612.47	$379.91
0113	Excision Lymphatic System	T	18.7496	$977.81	.....	$195.56
0114	Thyroid/Lymphadenectomy Procedures	T	36.1135	$1,883.36	$485.91	$376.67
0115	Cannula/Access Device Procedures	T	24.3211	$1,268.37	$459.35	$253.67
0116	Chemotherapy Administration by Other Technique Except Infusion	S	0.7752	$40.43	.....	$8.09
0117	Chemotherapy Administration by Infusion Only	S	3.6046	$187.98	$48.28	$37.60
0118	Chemotherapy Administration by Both Infusion and Other Technique.	S	5.4844	$286.02	$72.03	$57.20
0119	Implantation of Devices	T	89.3100	$4,657.61	.....	$931.52
0120	Infusion Therapy Except Chemotherapy	T	2.1802	$113.70	$30.75	$22.74
0121	Level I Tube changes and Repositioning	T	2.0833	$108.65	$43.80	$21.73
0122	Level II Tube changes and Repositioning	T	10.7459	$560.41	$114.93	$112.08
0123	Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant	S	6.4049	$334.02	.....	$66.80
0124	Revision of Implanted Infusion Pump	T	50.0861	$2,612.04	.....	$522.41
0125	Refilling of Infusion Pump	T	2.0639	$107.63	.....	$21.53
0130	Level I Laparoscopy	T	30.4644	$1,588.75	$659.53	$317.75
0131	Level II Laparoscopy	T	40.2026	$2,096.61	$1,001.89	$419.32
0132	Level III Laparoscopy	T	56.9948	$2,972.34	$1,239.22	$594.47
0140	Esophageal Dilation without Endoscopy	T	6.0948	$317.85	$107.24	$63.57
0141	Upper GI Procedures	T	7.4126	$386.57	$143.38	$77.31
0142	Small Intestine Endoscopy	T	8.1393	$424.47	$152.78	$84.89
0143	Lower GI Endoscopy	T	7.9165	$412.85	$186.06	$82.57
0146	Level I Sigmoidoscopy	T	3.4302	$178.89	$64.40	$35.78
0147	Level II Sigmoidoscopy	T	7.0153	$365.85	$79.46	$73.17
0148	Level I Anal/Rectal Procedure	T	3.4205	$178.38	$63.38	$35.68
0149	Level III Anal/Rectal Procedure	T	16.3756	$854.00	$293.06	$170.80
0150	Level IV Anal/Rectal Procedure	T	21.2398	$1,107.68	$437.12	$221.54
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	T	17.5093	$913.13	$245.46	$182.63
0152	Percutaneous Abdominal and Biliary Procedures	T	10.0288	$523.01	$131.28	$104.60
0153	Peritoneal and Abdominal Procedures	T	19.5441	$1,019.24	$410.87	$203.85
0154	Hernia/Hydrocele Procedures	T	25.7262	$1,341.65	$464.85	$268.33
0155	Level II Anal/Rectal Procedure	T	10.1936	$531.61	$188.89	$106.32
0156	Level II Urinary and Anal Procedures	T	2.9747	$155.13	$46.55	$31.03
0157	Colorectal Cancer Screening: Barium Enema	S	2.5387	$132.40	.....	$26.48
0158	Colorectal Cancer Screening: Colonoscopy	T	7.0638	$368.38	.....	$92.10
0159	Colorectal Cancer Screening: Flexible Sigmoidoscopy	S	2.3255	$121.28	.....	$30.32
0160	Level I Cystourethroscopy and other Genitourinary Procedures	T	6.3080	$328.97	$105.06	$65.79
0161	Level II Cystourethroscopy and other Genitourinary Procedures	T	15.7070	$819.14	$249.36	$163.83
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T	20.5906	$1,073.82	.....	$214.76
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	T	28.3714	$1,479.60	.....	$295.92
0164	Level I Urinary and Anal Procedures	T	1.1240	$58.62	$17.59	$11.72
0165	Level III Urinary and Anal Procedures	T	12.2672	$639.75	.....	$127.95
0166	Level I Urethral Procedures	T	15.4163	$803.98	$218.73	$160.80
0167	Level III Urethral Procedures	T	28.3230	$1,477.07	$555.84	$295.41

ADDENDUM A.—LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCS) WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS—Continued

[Calendar Year 2003]

APC	Group title	Status indicator	Relative weight	Payment rate	National unadjusted copayment	Minimum unadjusted copayment
0168	Level II Urethral Procedures	T	24.4665	$1,275.95	$405.60	$255.19
0169	Lithotripsy	T	44.0978	$2,299.74	$1,115.69	$459.95
0170	Dialysis	S	4.8352	$252.16	.....	$50.43
0179	Urinary Incontinence Procedures	T	104.3581	$5,442.38	$2,340.22	$1,088.48
0180	Circumcision	T	18.1004	$943.95	$304.87	$188.79
0181	Penile Procedures	T	29.2435	$1,525.08	$621.82	$305.02
0182	Insertion of Penile Prosthesis	T	95.4145	$4,975.96	.....	$995.19
0183	Testes/Epididymis Procedures	T	21.2592	$1,108.69	.....	$221.74
0184	Prostate Biopsy	T	3.6918	$192.53	$96.27	$38.51
0187	Miscellaneous Placement/Repositioning	X	3.9534	$206.17	$90.71	$41.23
0188	Level II Female Reproductive Proc	T	1.0465	$54.58	$11.95	$10.92
0189	Level III Female Reproductive Proc	T	1.5310	$79.84	$18.60	$15.97
0190	Surgical Hysteroscopy	T	19.0596	$993.98	$424.28	$198.80
0191	Level I Female Reproductive Proc	T	0.2035	$10.61	$3.08	$2.12
0192	Level IV Female Reproductive Proc	T	2.7228	$142.00	$39.11	$28.40
0193	Level V Female Reproductive Proc	T	14.4764	$754.96	$171.13	$150.99
0194	Level VI Female Reproductive Proc	T	18.0228	$939.91	$397.84	$187.98
0195	Level VII Female Reproductive Proc	T	23.7301	$1,237.55	$483.80	$247.51
0196	Dilation and Curettage	T	15.5035	$808.52	$338.23	$161.70
0197	Infertility Procedures	T	1.5697	$81.86	$33.06	$16.37
0198	Pregnancy and Neonatal Care Procedures	T	1.2597	$65.69	$32.19	$13.14
0199	Obstetrical Care Service	T	3.9146	$204.15	$57.16	$40.83
0200	Therapeutic Abortion	T	15.1838	$791.85	$307.83	$158.37
0201	Spontaneous Abortion	T	15.3097	$798.42	$329.65	$159.68
0202	Level VIII Female Reproductive Proc	T	45.5610	$2,376.05	$1,164.26	$475.21
0203	Level IV Nerve Injections	T	11.7924	$614.99	$276.76	$123.00
0204	Level I Nerve Injections	T	2.0251	$105.61	$40.13	$21.12
0206	Level II Nerve Injections	T	4.7867	$249.63	$75.55	$49.93
0207	Level III Nerve Injections	T	5.7654	$300.67	$123.69	$60.13
0208	Laminotomies and Laminectomies	T	38.4487	$2,005.14	.....	$401.03
0209	Extended EEG Studies and Sleep Studies, Level II	S	11.3369	$591.23	$280.58	$118.25
0212	Nervous System Injections	T	3.3139	$172.82	$79.53	$34.56
0213	Extended EEG Studies and Sleep Studies, Level I	S	3.2557	$169.79	$70.41	$33.96
0214	Electroencephalogram	S	2.2286	$116.22	$58.12	$23.24
0215	Level I Nerve and Muscle Tests	S	0.5814	$30.32	$15.76	$6.06
0216	Level III Nerve and Muscle Tests	S	2.8972	$151.09	$67.98	$30.22
0218	Level II Nerve and Muscle Tests	S	1.0077	$52.55	.....	$10.51
0220	Level I Nerve Procedures	T	15.8136	$824.70	.....	$164.94
0221	Level II Nerve Procedures	T	21.5208	$1,122.33	$463.62	$224.47
0222	Implantation of Neurological Device	T	227.7370	$11,876.71	.....	$2,375.34
0223	Implantation of Pain Management Device	T	41.0262	$2,139.56	.....	$427.91
0224	Implantation of Reservoir/Pump/Shunt	T	34.0302	$1,774.71	$453.41	$354.94
0225	Implantation of Neurostimulator Electrodes	S	139.3379	$7,266.61	.....	$1,453.32
0226	Implantation of Drug Infusion Reservoir	T	144.3474	$7,527.86	.....	$1,505.57
0227	Implantation of Drug Infusion Device	T	144.5122	$7,536.46	.....	$1,507.29
0228	Creation of Lumbar Subarachnoid Shunt	T	59.6207	$3,109.28	$696.46	$621.86
0229	Transcatherter Placement of Intravascular Shunts	T	57.4599	$2,996.59	$771.23	$599.32
0230	Level I Eye Tests & Treatments	S	0.7364	$38.40	$14.97	$7.68
0231	Level III Eye Tests & Treatments	S	2.1705	$113.19	$50.94	$22.64
0232	Level I Anterior Segment Eye Procedures	T	4.4960	$234.47	$103.17	$46.89
0233	Level II Anterior Segment Eye Procedures	T	13.4202	$699.88	$266.33	$139.98
0234	Level III Anterior Segment Eye Procedures	T	20.4259	$1,065.23	$511.31	$213.05
0235	Level I Posterior Segment Eye Procedures	T	5.0871	$265.30	$73.44	$53.06
0236	Level II Posterior Segment Eye Procedures	T	19.4278	$1,013.18	.....	$202.64
0237	Level III Posterior Segment Eye Procedures	T	33.2647	$1,734.79	$818.54	$346.96
0238	Level I Repair and Plastic Eye Procedures	T	2.9747	$155.13	$58.96	$31.03
0239	Level II Repair and Plastic Eye Procedures	T	6.8119	$355.25	$115.94	$71.05
0240	Level III Repair and Plastic Eye Procedures	T	16.3078	$850.47	$315.31	$170.09
0241	Level IV Repair and Plastic Eye Procedures	T	20.6294	$1,075.84	$384.47	$215.17
0242	Level V Repair and Plastic Eye Procedures	T	28.0517	$1,462.92	$597.36	$292.58
0243	Strabismus/Muscle Procedures	T	19.9705	$1,041.48	$431.39	$208.30
0244	Corneal Transplant	T	35.6290	$1,858.09	$803.26	$371.62
0245	Level I Cataract Procedures without IOL Insert	T	14.5442	$758.49	$251.21	$151.70
0246	Cataract Procedures with IOL Insert	T	22.2379	$1,159.73	$495.96	$231.95
0247	Laser Eye Procedures Except Retinal	T	4.7092	$245.59	$104.31	$49.12
0248	Laser Retinal Procedures	T	4.2925	$223.86	$95.08	$44.77
0249	Level II Cataract Procedures without IOL Insert	T	26.7242	$1,393.69	$524.67	$278.74
0250	Nasal Cauterization/Packing	T	1.6376	$85.40	$29.89	$17.08